CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203312Orig1s000

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 20, 2014
Application Type and Number:	NDA 203312
Product Name and Strength:	Rytary (carbidopa and levodopa) extended-release capsules, carbidopa 23.75 mg and levodopa 95 mg, carbidopa 36.25 mg and levodopa 145 mg, carbidopa 48.75 mg and levodopa 195 mg, carbidopa 61.25 mg and levodopa 245 mg
Product Type:	Multi-ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Impax Laboratories, Inc.
Submission Date:	August 21, 2014
Panorama #:	2014-26200
DMEPA Primary Reviewer:	Justine Harris, RPh
DMEPA Acting Team Leader:	Tingting Gao, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Rytary, 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 did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

The sponsor previously submitted the proposed proprietary name, [(b) (4)] under NDA 203312 on January 17, 2012. An amendment to the request for proprietary name review was submitted on February 14, 2012 with updated dosage and frequency of administration instructions. On February 10, 2012, the Division of Neurology Products (DNP) identified the concern that [(b) (4)] DMEPA evaluated this concern and subsequently held a teleconference with Impax on March 30, 2012 to discuss this safety concern. On April 5, 2012, Impax submitted an amendment to the request for proprietary name review to change the [(b) (4)] The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Rytary, acceptable in OSE Review #2012-175, dated April 12, 2012. In this review, DMEPA also evaluated the need for a modifier with the name (e.g., ER, XR, XL) to convey that Rytary is an extended-release dosage form. We concluded that there was no compelling evidence to support the necessity to request a modifier for the proposed proprietary name, Rytary, at that time and if approved, DMEPA would monitor for medication errors where the proprietary name is a contributing factor to the error.[1]

The sponsor resubmitted the name, Rytary, for review on August 21, 2014 and confirmed that none of the product characteristics had changed from those stated in the previously submitted proprietary name reviews.

1.2 PRODUCT INFORMATION

The following product information is provided in the January 13, 2012 and April 4, 2012 proprietary name submissions.

- Intended Pronunciation: rye tar' ee
- Active Ingredient: carbidopa and levodopa
- Indication of Use: [(b) (4)] Parkinson's disease [(b) (4)], postencephalatic parkinsonism, and [(b) (4)] parkinsonism following carbon monoxide [(b) (4)] or manganese intoxication

[1] Neshiewat, J. Proprietary Name Review for Rytary (NDA203312). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2012 APR 12. 70 p. OSE RCM No.: 2012-175.

- Route of Administration: oral
- Dosage Form: Extended-release capsules
- Strength: carbidopa 23.75 mg and levodopa 95 mg,
  carbidopa 36.25 mg and levodopa 145 mg,
  carbidopa 48.75 mg and levodopa 195 mg
  carbidopa 61.25 mg and levodopa 245 mg
- Dose and Frequency: (b) (4)
- How Supplied: (b) (4) and 100 count and 240 count bottles
- Storage: Room Temperature
- Container and Closure Systems: not provided

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 does not misbrand the proposed product. DMEPA and the Division of Neurology Products (DNP) 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[2].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Rytary 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]USAN stem search conducted on September 8, 2014.

2.2.3 FDA Name Simulation Studies

Ninety-nine practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline.

Sixty-one participants (60 in the written prescription studies and 1 in the verbal prescription study) interpreted the name correctly. Fourteen participants misinterpreted the letter string 'Ry-' for 'Re-' (14 in the verbal prescription study and 0 in the written prescription study.) Fifteen participants in the prescription study misinterpreted the letter string '-Ry-' for 'Ri-' (10 in the verbal prescription study and 5 in the written prescription study.) Twenty-two participants in the verbal prescription study misinterpreted the ending letter string '-tary' for '-tari'. 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, September 10, 2014 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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[3] organized as highly similar, moderately similar, or low similarity for further evaluation. Table 1 also includes names identified from the FDA Simulation Study.

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%	50
Low similarity name pair: combined match percentage score ≤49%	0

[3] POCA search conducted on September 10, 2014.

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

Our analysis of the 51 names contained in Table 1 determined than none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on October 15, 2014. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on October 15, 2014, they stated no additional concerns with the proposed proprietary name, Rytary.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-796-0097.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your August 21, 2014 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 DNCE. OPDP or DNCE 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 DNCE 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. [4]

[4] 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 does 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.

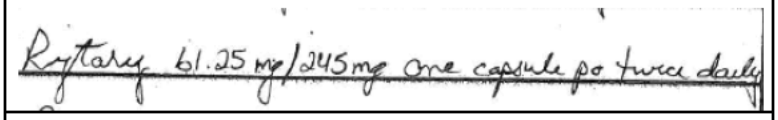
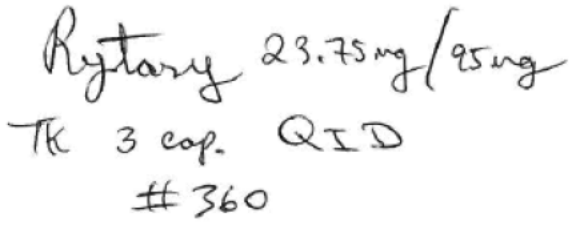
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Rytary Study (Conducted on September 5, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Rytary 23.75 mg/95 mg Take three caps 4 times daily Disp # 360

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report) conducted September 5, 2014

260 People Received Study
99 People Responded

Study Name: Rytary

Total	31	31	37	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
RATARI	0	2	0	2
REITARI	0	1	0	1
RETARI	0	11	0	11
RETARY	0	1	0	1
RETIREE	0	1	0	1
RIGTARY	0	0	1	1

RIJTARY	0	0	1	1
RITARI	0	4	0	4
RITARIE	0	1	0	1
RITARY	0	3	1	4
RITERA	0	1	0	1
RITIRIE	0	1	0	1
RIYTARY	0	0	2	2
(b) (4)	0	4	0	4
RYTARIZ	0	0	1	1
RYTARQ	0	0	1	1
RYTARY	30	1	30	61
RYTARYZ	1	0	0	1

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

No.	**Proposed name: Rytary** **Strength(s): 23.75/95 mg; 36.25/145 mg; 48.75/195 mg; 61.25/245 mg** **Usual Dose: 1 to 3 caps 2 to 4 times per day**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion**
1.	(b) (4) ***	90	Name withdrawn and alternate name Rytary submitted which is subject of this review

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.	ERYPAR	67
2.	Ry-Tann	62
3.	RITALIN	58
4.	(b) (4) ***	58

5.	Rotarix	58
6.	RIDAURA	57
7.	RIFATER	57
8.	ERY-TAB	56
9.	Zetar	56
10.	RESTORIL	55
11.	RETIN-A	54
12.	REZIRA	54
13.	(b) (4)	54
14.	(b) (4)	54
15.	(b) (4)	53
16.	REYATAZ	52
17.	Retaane***	52
18.	Rederm	52
19.	Reluri	52
20.	Ricola	52
21.	Rynesa	52
22.	Respa-BR	51
23.	Repatha***	50
24.	Altaryl	50
25.	Relera	50
26.	Ry-T-12	50

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: Rytary** **Strength(s): 23.75/95 mg; 36.25/145 mg; 48.75/195 mg; 61.25/245 mg** **Usual Dose: 1 to 3 caps 2 to 4 times per day**	**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.	Rextoro***	52	The prefix and suffix of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
1.	N/A	

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.	(b) (4)***	65	Proposed Proprietary Name found unacceptable by DMEPA (OSE RCM # 2011-321). Product approved under new proprietary name Stendra (OSE 2012-597)
2.	(b) (4)***	64	Proposed Proprietary Name found unacceptable by DMEPA (OSE RCM # 2011-321). Product approved under new proprietary name Stendra (OSE 2012-597)
3.	RAXAR	58	Product discontinued; no generics available
4.	(b) (4)***	56	This is a secondary proposed proprietary name and the product was approved under proprietary name Lumason (OSE #2013-2105)

5.	Re Tann	56	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
6.	Radri	54	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
7.	(b) (4) ***	53	Dual Proposed Proprietary Name found unacceptable (OSE#2012-581); entire application withdrawn by the Applicant
8.	Raphtre	53	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
9.	Respa AR	52	Product discontinued: no generics available
10.	Respa-A.R.	52	Product discontinued: no generics available
11.	Ry-Tuss	52	deactivated per RB; no generics found
12.	(b) (4) ***	50	Secondary name for Kynapid which was found acceptable OSE # 2007-1682 ((b) (4))
13.	Polytar	50	Product discontinued; no generics available
14.	Rovera	50	veterinary product
15.	Rynessa	50	Name Identified in POCA in RxNorm. Unable to find product characteristics in commonly used databases.

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

No.	Name	POCA Score (%)
1.	VYTORIN	58
2.	Vetoryl	58
3.	Scytera	55
4.	Lutera	54
5.	Trital	54
6.	Vetadryl	52
7.	Urimar	51
8.	Tritan	50

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JUSTINE HARRIS
10/20/2014

TINGTING N GAO
10/20/2014

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review--Final

Date:	December 18, 2012
Reviewer:	Julie Neshiewat, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Drug Name and Strengths:	Rytary (Carbidopa and Levodopa) Extended-release Capsules Carbidopa 23.75 mg and Levodopa 95 mg, Carbidopa 36.25 mg and Levodopa 145 mg, Carbidopa 48.75 mg and Levodopa 195 mg, Carbidopa 61.25 mg and Levodopa 245 mg
Application Type/Number:	NDA 203312
Applicant/Sponsor:	Impax Pharmaceuticals
OSE RCM #:	2012-2661

*** This document contains proprietary and confidential information that should not be released to the public.***

CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Rytary, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Rytary, acceptable in OSE Review # 2012-175 dated April 12, 2012 and OSE Review # 2012-1623 dated August 13, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, the Division of Medication Error Prevention and Analysis (DMEPA) searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review, we used the same search criteria described in OSE Review # 2012-175. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience related to proprietary name confusion. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded no new names thought to look or sound similar to Rytary and represent a potential source of drug name confusion.

Additionally, DMEPA searched the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN update. The Safety Evaluator did not identify any USAN stems in the proposed proprietary name, as of December 11, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on November 16, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Rytary, did not identify any vulnerabilities that would result in medication errors. Thus, DMEPA has no objection to the proprietary name, Rytary, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Neurology Products (DNP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Laurie Kelley, OSE project manager, at 301-796-5068.

4 REFERENCES

1. **Neshiewat, J. OSE Review # 2012-175: Proprietary Name Review for Rytary. April 12, 2012.**

2. **Neshiewat, J. OSE Review # 2012-1623: Proprietary Name Final Review for Rytary. August 13, 2012.**

3. ***Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)***

   Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

4. ***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.

5. ***Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request***

   Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JULIE V NESHIEWAT
12/18/2012

IRENE Z CHAN
12/18/2012

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review--Final

Date:	August 13, 2012
Reviewer:	Julie Neshiewat, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Drug Name and Strengths:	Rytary (Carbidopa and Levodopa) Extended-release Capsules Carbidopa 23.75 mg and Levodopa 95 mg, Carbidopa 36.25 mg and Levodopa 145 mg, Carbidopa 48.75 mg and Levodopa 195 mg, Carbidopa 61.25 mg and Levodopa 245 mg
Application Type/Number:	NDA 203312
Applicant/Sponsor:	Impax Pharmaceuticals
OSE RCM #:	2012-1623

*** This document contains proprietary and confidential information that should not be released to the public.***

CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Rytary, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Rytary, acceptable in OSE Review # 2012-175 dated April 12, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, the Division of Medication Error Prevention and Analysis (DMEPA) searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review, we used the same search criteria described in OSE Review # 2012-175. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience related to proprietary name confusion. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded no new names thought to look or sound similar to Rytary and represent a potential source of drug name confusion.

Additionally, DMEPA searched the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN update. The Safety Evaluator did not identify any USAN stems in the proposed proprietary name, as of August 10, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on August 3, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Rytary, did not identify any vulnerabilities that would result in medication errors. Thus, DMEPA has no objection to the proprietary name, Rytary, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Neurology Products (DNP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Laurie Kelley, OSE project manager, at 301-796-5068.

4 REFERENCES

1. **Neshiewat, J. OSE Review # 2012-175: Proprietary Name Review for Rytary. April 12, 2012.**

2. ***Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)***

   Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

3. ***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.

4. ***Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request***

   Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JULIE V NESHIEWAT
08/13/2012

IRENE Z CHAN
08/13/2012

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review

Date:	April 12, 2012
Reviewer:	Julie Neshiewat, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Deputy Director:	Kellie Taylor, PharmD, MPH Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strengths:	Rytary (Carbidopa and Levodopa) Extended-release Capsules Carbidopa 23.75 mg and Levodopa 95 mg, Carbidopa 36.25 mg and Levodopa 145 mg, Carbidopa 48.75 mg and Levodopa 195 mg, Carbidopa 61.25 mg and Levodopa 245 mg
Application Type/Number:	NDA 203312
Applicant/Sponsor:	Impax Pharmaceuticals
OSE RCM #:	2012-152

*** This document contains proprietary and confidential information that should not be released to the public.***

CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Rytary, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

This application is a 505(b)(2) application, and the reference listed drugs are Sinemet (Carbidopa and Levodopa) Tablets, NDA 017555, Sinemet CR (Carbidopa and Levodopa) Extended-release Tablets, NDA 019856, Lodosyn (Carbidopa) Tablets, NDA 017830, and Stalevo (Carbidopa, Levodopa, and Entacapone) Tablets, NDA 021485.

Impax Laboratories submitted the proposed proprietary name, (b) (4), for Carbidopa and Levodopa Extended-release Capsules on September 7, 2011 under IND 102887. On October 17, 2011, Impax Laboratories submitted an amendment to the request for proprietary name review to update the strengths and maximum daily doses for both carbidopa and levodopa as requested by the Division of Medication Error Prevention and Analysis (DMEPA). While reviewing (b) (4) under the IND application, Impax Laboratories submitted the proposed proprietary name, (b) (4), under NDA 203312 on January 17, 2012. An amendment to the request for proprietary name review was submitted on February 14, 2012 with updated dosage and frequency of administration instructions. The request for proprietary name review under IND 102887 was withdrawn on February 27, 2012.

On February 10, 2012, the Division of Neurology Products (DNP) identified the concern that (b) (4) DMEPA evaluated this concern and subsequently held a teleconference with Impax Laboratories on March 30, 2012 to discuss the safety concerns with the proposed proprietary name (b) (4), and provide potential solutions for moving forward. DMEPA expressed concern that (b) (4) During the teleconference, DMEPA stated that the Applicant could submit an amendment to the request for proprietary name review if Rytary or (b) (4) is chosen. On April 5, 2012, Impax Laboratories submitted an amendment to the request for proprietary name review to change th (b) (4) .

1.2 PRODUCT INFORMATION

The following product information is provided in the February 14, 2012 proprietary name submission.

- Active Ingredient: Carbidopa and Levodopa

- Indication of Use: [redacted] Parkinson's disease, postencephalatic parkinsonism, and [redacted] parkinsonism following carbon monoxide or manganese intoxication
- Route of Administration: Oral
- Dosage Form: Extended-release Capsules
- Strength: Carbidopa 23.75 mg and Levodopa 95 mg, Carbidopa 36.25 mg and Levodopa 145 mg, Carbidopa 48.75 mg and Levodopa 195 mg, and Carbidopa 61.25 mg and Levodopa 245 mg
- Dose and Frequency of Administration: [redacted] For patients who have difficulty swallowing intact capsules, the capsules can be opened and sprinkled on a small amount of [redacted] such as applesauce. The capsule contents, however, should not be chewed.
- How Supplied: 100-count and 240-count bottles for retail; 25-count bottles for professional samples
- Storage: Room temperature
- Container and Closure System: Opaque white high-density polyethylene bottles with matching white [redacted] closures sealed with an induction inner-seal

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Neurology Products (DNP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects of the name were considered in the overall safety evaluation.

2.2.1 United States Adopted Names (USAN) SEARCH

The March 28, 2012 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Rytary, is not derived from any meaning. Rytary is an extended-release formulation comprised of two active ingredients, carbidopa and levodopa. The Applicant does not include a modifier with the name (e.g., ER, XR, XL) to convey that Rytary is an extended-release dosage

form. There is both an immediate-release and extended-release formulation of this combination drug product currently marketed by another firm under the proprietary names Sinemet and Sinemet CR respectively. Therefore, we have evaluated whether or not the proposed name requires a modifier to signal the extended-release nature of the product (see Discussion – Section 3).

2.2.3 FDA Name Simulation Studies

Thirty-four practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with, appear, or sound similar to any currently marketed products. The verbal study indicates that the 'y' in Rytary sounds similar to 'i.' The written study indicates that the 'y' at the sixth position of Rytary can be misread as a 'g.' See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Rytary. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Rytary, identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the phonetically similar names identified by the (b) (4) for (b) (4) that were not identified by DMEPA and require further evaluation. We excluded the orthographically similar names identified in the external name study since the amended proprietary name, Rytary, has an additional down stroke at the sixth position, (b) (4)

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)

Name	*Source*	*Name*	*Source*	*Name*	*Source*
Look Similar					
Hytone	EPD	(b) (4) ***	EPD	Epifoam	Primary reviewer
Hytrin	EPD	Ry-Tann	EPD	Nystop	Primary reviewer
Kytril	EPD	Rythmol	EPD	Zytiga	Primary reviewer

*** This document contains proprietary and confidential information that should not be released to the public.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Look Similar					
Pylera	EPD	Rytron B	EPD	Zuplenz	Primary reviewer
Pytest	EPD	Ry-Tuss	EPD	Hylenex	Primary reviewer
Reyataz	EPD	(b) (4)***	EPD	Butex Forte	Primary reviewer
Rybix	EPD	Hytan	Primary reviewer	Dylix	Primary reviewer
Rybix ODT	EPD	Extina	Primary reviewer	Dytan	Primary reviewer
(b) (4)***	EPD	Exforge	Primary reviewer	Dytuss	Primary reviewer
Raptiva	Primary reviewer	Lyteca	Primary reviewer	Pylori-Chek Breath Test	EPD
(b) (4)***	Primary reviewer	Nutrox	EPD	Reglan	EPD
(b) (4)***	Primary reviewer	Nyotran	Primary reviewer	Rubex	Primary reviewer
(b) (4)***	Primary reviewer	Pylora	Primary reviewer	Rufen	Primary reviewer
Rulox	Primary reviewer	Rutin	EPD	Ru-Tuss	EPD
Rydex	EPD	Vytone	Primary reviewer	Zylan	Primary reviewer
Zylox	Primary reviewer	Zytaze	Primary reviewer	(b) (4)***	Primary reviewer
(b) (4)***	Primary reviewer	Dyline GG	Primary reviewer	Hyflex	Primary reviewer

*** This document contains proprietary and confidential information that should not be released to the public.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Look Similar					
Dyflex	Primary reviewer	[redacted]			
Sound Similar					
Reluri	External study	Tysabri	External study	Rhatany	Primary reviewer
Ritalin	External study	Ridaura	EPD	L. reuteri	Primary reviewer
Look and Sound Similar					
Vytorin	EPD for look alike; External study for look alike and sound alike	Rotarix	EPD for look alike; External study for look alike and sound alike	Rynatan	EPD for look alike; External study for look alike and sound alike
Restasis	External study	Restoril	External study	Retisert	External study

Our analysis of the 64 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 64 names will not pose a risk for confusion as described in Appendices D through E.

2.2.7 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on April 9, 2012. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology Products on April 9, 2012, they stated no additional concerns with the proposed proprietary name, Rytary.

3 DISCUSSION

As proposed, the Applicant does not include a modifier with the name (e.g., ER, XR, XL) to convey that Rytary is an extended-release dosage form. There is both an immediate-release and extended-release formulation of this combination drug product currently marketed by another firm under the proprietary names Sinemet and Sinemet CR respectively, along with several generic products marketed under the established name.

Sinemet, the branded product, is an immediate release tablet that is not scored although the labeling references the use of one-half tablet; however, when Sinemet was first approved, the tablet was scored and could be split. As such, there are generic products available that are scored and can be divided. Sinemet CR, the branded product, is a sustained release product that is not scored and cannot be crushed or chewed; however, when Sinemet CR was first approved, the 50 mg/200 mg tablet was scored and could be split. As such, there are generic products available that are scored. In February 2011, the FDA approved changes to Sinemet CR that included removing the tablet scoring and updating the insert labeling so that references to taking half of the 50 mg/200 mg sustained release tablet were removed.

In the case of Sinemet and Sinemet CR, the Applicant used a modifier to distinguish the two formulations with the same root name made by the same Applicant, which is a common naming convention. This differs from our product because Impax does not currently market an immediate-release formulation of this combination drug product that it needs to distinguish itself from; therefore, a modifier may not be necessary.

However, we evaluated whether the lack of modifier raises a potential safety concern, specifically if practitioners or patients were to assume the Rytary product is an immediate-release dosage form because no modifier is present in the proprietary name to signal the extended-release nature of the product. Therefore, we evaluated errors associated with currently marketed products to consider whether a modifier may be appropriate for this drug to convey the extended-release properties of this product.

First, we identified extended-release products approved without a modifier in the proprietary name and reviewed documented errors relating to wrong technique and wrong frequency of administration. Wrong technique errors involved patients or practitioners, chewing, splitting, opening, or crushing the extended-release oral dosage forms when these products were intended to be administered intact. Wrong frequency errors involved the administration of the extended-release dosage form at intervals more frequent than labeled, (e.g. taking a once daily drug twice a day). Wrong technique and wrong frequency errors occurred despite the presence of clear labeling directives to administer the products intact and at the given intervals. Additionally, based on the case narratives we were unable to determine a definitive root cause of the errors.

With respect to wrong technique errors, we do not believe Rytary poses the same risk for wrong technique errors that was identified above. Rytary can be manipulated by opening and sprinkling its contents over applesauce for administration, unlike the other products we reviewed that were intended to be administered intact only. We reviewed the Institute for Safe Medication Practices' (ISMP) list of "Oral Dosage Forms That Should Not Be Crushed" to identify if a modifier exists that could possibly convey that an extended-release dosage form can be manipulated. We focused our review on those names with modifiers that are commonly used to denote extended-release (e.g. ER, SR, CR, XR, XL, LA,), since the Institute of Medicine has charged FDA and Industry to standardize abbreviations to the greatest extent possible. Our review found that this list contains a nearly equal number of extended-release drug products in which the proprietary name contains a modifier (n = 82) and extended-release products with proprietary names without modifiers (n = 84). Based on this information, we conclude that there is no

standard single modifier currently on the market today that speaks to whether an extended-release product can or cannot be manipulated prior to administration.

Moreover, with respect to the potential for wrong frequency of administration errors, we do not anticipate that Rytary is prone to be administered at the wrong frequency of administration. The existing formulations, both immediate release and extended-release for this combination drug product, already overlap in frequency of administration since either can be dosed multiple times a day. This is similar to Rytary, which can be dosed three to five times daily. Therefore, we find that the risk of Rytary being administered at the wrong frequency is minimal, irrespective of the inclusion of a modifier in the proprietary name. While we recognize the currently marketed extended-release formulation of carbidopa and levodopa, Sinemet CR, can be administered twice daily, which is not labeled for Rytary, our research has not identified a modifier that can appropriately address such a specific difference.

In addition, the strengths of Rytary do not overlap and are not achievable with the strengths of the currently marketed immediate-release and extended-release formulations of this combination drug product. Therefore, we believe the differences in strength also minimize the risk of confusion when the products are prescribed in the case that the formulation descriptor (i.e. extended-release) is omitted or overlooked.

Given the totality of the factors considered above, there is no compelling evidence to support the necessity to request a modifier for the proposed proprietary name, (b) (4) at this time. If approved, DMEPA will monitor for medication errors where the proprietary name is a contributing factor to the error.

4 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Laurie Kelley, OSE project manager, at 301-796-5068

4.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Rytary, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your February 14, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The conclusions upon re-review are subject to change.

5 REFERENCES

1. ***Micromedex Integrated Index (http://csi.micromedex.com)***

   Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

   POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO (http://factsandcomparisons.com)***

   Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

   DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***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.

6. ***Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)***

   Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

7. ***U.S. Patent and Trademark Office (http://www.uspto.gov)***

   USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)***

   Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. ***Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com)***

   The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

10. ***Natural Medicines Comprehensive Databases (www.naturaldatabase.com)***

    Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

11. ***Access Medicine (www.accessmedicine.com)***

    Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. ***USAN Stems (http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml)***

    USAN Stems List contains all the recognized USAN stems.

13. ***Red Book (www.thomsonhc.com/home/dispatch)***

    Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

14. ***Lexi-Comp (www.lexi.com)***

    Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

15. ***Medical Abbreviations (www.medilexicon.com)***

    Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.

16. ***CVS/Pharmacy (www.CVS.com)***

    This database contains commonly used over the counter products not usually identified in other databases.

17. ***Walgreens (www.walgreens.com)***

    This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a Metasearch engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, 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.). 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. [1]

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. 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. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

---

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[2]

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

[2] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	**Considerations when Searching the Databases**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers gather CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

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.

4. 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.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[3] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

[3] Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?"***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

> ***"Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?"***

The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

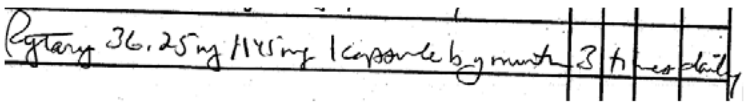
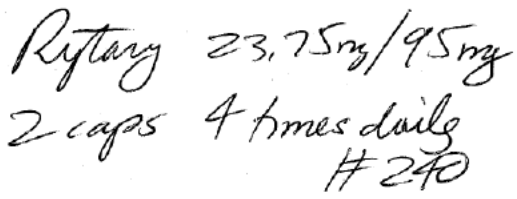
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Rytary	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'R'	B, D, K, P, Pr	wr
lower case 'r'	e, l, n, s, v, z, i	
lower case 'y'	f, g, j, p, q, u, v, x, z	e, i
lower case 't'	f, l, x	d
lower case 'a'	c, ce, ci, cl, d, e, el, er, o, u, x	
lower case 'r'	e, l, n, s, v, z, i	
lower case 'y'	f, g, j, p, q, u, v, x, z	e, i

Appendix C: Prescription Simulation Samples and Results

Figure 1. Rytary Study (Conducted on *March 16, 2012*)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  	Rytary 23.75 mg/95 mg Take two caps orally QID # 240
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

84 People Received Study

34 People Responded

Study Name: Rytary

Total	9	10	15	34
INTERPRETATION	**INPATIENT**	**VOICE**	**OUTPATIENT**	**TOTAL**
RITARI	0	5	0	5
RITARY	1	0	0	1
RYTARG	0	0	2	2
RYTARGY	1	0	0	1
RYTARY	0	3	0	3
RYTARY	6	0	12	18
RYTARY 36.25 MG/145 MG	1	0	0	1
RYTARY 23.75MG/95MG	0	0	1	1
RYTORI	0	1	0	1
VITARI	0	1	0	1

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

	Proprietary Name	Active Ingredient	Similarity to Rytary	Failure preventions
1	(b) (4)***	ceftaroline	Look alike	(b) (4)*** was an alternate name for the proposed name (b) (4), bu (b) (4)*** was not officially submitted as a request for proprietary name review. (b) (4)*** was not evaluated by DMEPA. The product is now marketed under the name Teflaro.
2	(b) (4)***	oxycodone	Look alike	Proposed proprietary name found unacceptable by DMEPA (OSE # 01-0114). Product approved under new proprietary name Roxicodone.
3	Rytron B	ferrous sulfate, thiamine, riboflavin	Look alike	Name identified in the Micromedex database. Unable to find product characteristics in commonly used drug databases.
4	(b) (4)***	lacosamide	Look alike	Proposed proprietary name found unacceptable by DMEPA (OSE # 06-103). Product approved under new proprietary name Vimpat.
5	(b) (4)***	isotretinoin	Look alike	Proposed proprietary name found unacceptable by DMEPA (OSE # 01-0111-2). Product approved under new proprietary name Sotret.
6	(b) (4)	tramadol	Look alike	This proposed proprietary name was withdrawn by the Applicant. This product is now marketed under the name Rybix ODT. Rybix ODT is evaluated in Appendix E.
7	Restasis	cyclosporine	Look alike and sound alike	The pair have sufficient orthographic and phonetic differences.
8	Restoril	temazepam	Look alike and sound alike	The pair have sufficient orthographic and phonetic differences.

*** This document contains proprietary and confidential information that should not be released to the public.

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

	Proprietary Name	Active Ingredient	Similarity to Rytary	Failure preventions
9	Retisert	fluocinolone acetonide	Look alike and sound alike	The pair have sufficient orthographic and phonetic differences.
10	Tysabri	natalizumab	Sound alike	The pair have sufficient phonetic differences.
11	Rhatany		Sound alike	Name identified in the Natural Medicines database. Unable to find product characteristics in commonly used drug databases.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
12	Hytone (Hydrocortisone) Cream, Solution, Lotion, and Ointment Strength: 1% cream and solution, 2.5% cream, lotion, and ointment Dosage: Apply to affected areas no more than three to 4 times daily	Orthographic: The first letter 'R' and 'H' look similar when scripted. Both names contain a down stroke 'y' at the second position and a cross stroke 't' at the third position. Additionally, the letter pair 'ar' in Rytary and 'on' in Hytone and 'ar' look similar when scripted. Frequency of administration: Both products can be administered three or four times daily.	Orthographic: Rytary contains a down stroke 'y' at the sixth position vs. Hytone does not contain a down stroke letter at the sixth position. Strength: Both products have multiple strengths, which do not overlap and are not achievable. Dosage: Rytary will be prescribed as "Take XX capsules" vs. Hytone will be prescribed as "Apply XX amount." Dosage form: Rytary is only available as capsules, which does not overlap with the dosage forms of Hytone – cream, solution, lotion, and ointment.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
13	Hytrin (Terazosin) Capsules and Tablets Strength: 1 mg, 2 mg, 5 mg, 10 mg Dosage: 1 capsule or tablet once or twice daily	Orthographic: The first letter 'R' and 'H' may look similar when scripted. Both names contain a down stroke 'y' at the second position and a cross stroke 't' at the third position.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Hytrin does not contain a down stroke letter at the sixth position. Strength: Both products have multiple strengths, which do not overlap and are not achievable.
14	Reyataz (Atazanavir) Capsules Strength: 100 mg, 150 mg, 200 mg, 300 mg Dosage: 1 capsule by mouth once daily	Orthographic: Both names begin with 'R' contain a down stroke 'y' and a cross stroke 't.' Additionally, the last letter 'y' in Rytary may look similar to the last letter 'z' in Reyataz, if scripted as a down stroke letter.	Orthographic: Before the upstroke 't,' the prefix 'Reya' appears longer than the prefix 'Ry' when scripted. Strength: Both products have multiple strengths, which do not overlap and are not achievable.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
15	(b) (4)		

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
16	(b) (4)		

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
17	Hytan (Chlorpheniramine and Hydrocodone) Suspension Strength: chlorpheniramine 4 mg and hydrocodone 5 mg per 5 mL suspension Dosage: 1 mL to 10 mL every 6 to 8 hours as needed	Orthographic: The first letter 'R' and 'H' may look similar when scripted. Both names contain a down stroke letter 'y' at the second position, a cross stroke letter 't' at the third position, and the letter 'a' at the fourth position.	Orthographic: Rytary contains a down stroke letter 'y' at the last position vs. Hytan does not contain a down stroke letter at the last position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Hytan is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Hytan.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
18	Extina (Ketoconazole) Foam Strength: 2% Dosage: Apply to affected areas twice daily	Orthographic: The first letters 'ry' and 'ex' may look similar when scripted. Both names contain a cross stroke letter 't' at the third position.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Extina does not contain a down stroke letter at the sixth position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Extina is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap with the strength of Extina. Dosage: Rytary will be prescribed as "Take XX capsules" vs. Extina will be prescribed as "Apply XX amount."

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
19	Hylenex (Hyalurondiase) Injection Strength: 100 units per mL Dosage: 15 units to each 100 mL of intravenous fluid to be administered subcutaneously or 150 units followed by subcutaneous isotonic fluid administration; 75 units over each scapula followed by injection of contrast medium at the same site	Orthographic: The first letter 'R' and 'H' look similar when scripted. Both names contain a down stroke letter 'y' at the second position that is immediately followed by an upstroke letter. Additionally, the letter pair 'en' in Hylenex and 'ar' in Rytary look similar when scripted.	Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Hylenex is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap with the strength or dose of Hylenex.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
20	Rubex (doxorubicin) Injection Strength: 50 mg, 100 mg Dosage: *Most commonly used dose schedule when used as a single agent:* 20 mg/m² to 75 mg/m² as a single intravenous dose on days 1, 2, and 3 of a 4-week cycle, on days 1 and 8 each month, once weekly, or once every 3 weeks.	Orthographic: Both names begin with 'R' and contain an upstroke letter at the third position. The second position 'u' in Rubex may look similar to the second position 'y' in Rytary. Additionally, the letter pair 'ex' in Rubex may look similar to 'ry' in Rytary. Dosage: A prescription for Rubex would be individualized based on the patient's weight, which could overlap with the dose for Rytary.	Orthographic: The upstroke letter 't' in Rytary at the third position also provides a cross stroke letter vs. Rubex does not contain a cross stroke letter at the third position. Additionally, Rytary contains two letters between the upstroke letter at the third position and the down stroke letter at the last position vs. Rubex contains one letter between the upstroke letter at the third position and the letter at the last position. Frequency of administration: Rubex is administered on specific days of a cycle, once weekly, or once every 3 weeks vs. Rytary is administered three to five times daily.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
21	Nyotran (nystatin liposomal) Injection Strength: 50 mg, 100 mg Dosage: 0.25 mg/kg/day to 4 mg/kg/day intravenously	Orthographic: The first letter 'n' and 'r' look similar when scripted. Both names contain a down stroke letter 'y' at the second position, and an upstroke 't' in the infix. Additionally, the letter string 'an' in Nyotran and 'ar' in Rytary look similar when scripted. Dosage: Since Nyotran has a wide dosage range of 0.25 mg/kg to 4 mg/kg intravenously, the dosage of Nyotran has potential to overlap with a strength of Rytary.	Orthographic: Nyotran contains a rounded letter 'o' between the down stroke letter 'y' and upstroke letter 't' vs. the down stroke letter 'y' is followed by the upstroke letter 't' in Rytary. Rytary contains a down stroke letter 'y' at the sixth position vs. Nyotran does not contain a down stroke in the suffix

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
22	Exforge (Amlodipine and Valsartan) Tablets Strength: amlodipine 5 mg and valsartan 160 mg, amlodipine 5 mg and valsartan 320 mg, amlodipine 10 mg and valsartan 160 mg, amlodipine 10 mg and valsartan 320 mg Dosage: 1 tablet by mouth once daily	Orthographic: The first letters 'ry' and 'ex' may look similar when scripted. Additionally, both names contain a cross stroke letter at the third position, the letter 'r' at the fifth position, and a down stroke letter at the sixth position.	Strength: Both products have multiple strengths, which do not overlap and are not achievable

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
23	Dyflex (Dyphylline and Guaifenesin) Tablets Strength: Dyphylline 200 mg and Guaifenesin 200 mg Dosage: ½ to 1 tablet by mouth three to four times daily	Orthographic: The first letter 'D' and 'R' look similar when scripted. Both names contain a down stroke letter 'y' at the second position that is immediately followed by a cross stroke letter at the third position. The letter pair 'ex' in Dyflex and 'ry' in Rytary may look similar when scripted. Dosage: Both products can be prescribed take 1 three times daily.	Orthographic: Dyflex contains an upstroke letter at the fourth position vs. Rytary does not contain an upstroke letter at the fourth position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Dyflex is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Dyflex.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
24	Hyflex (Acetaminophen and Phenyltoloxamine Citrate) Tablets Strength: Acetaminophen 650 mg and Phenyltoloxamine Citrate 60 mg Dosage: ½ to one tablet by mouth every 4 hours	Orthographic: The first letter 'H' and 'R' look similar when scripted. Both names contain a down stroke letter 'y' at the second position that is immediately followed by a cross stroke letter at the third position. The letter pair 'ex' in Hyflex and 'ry' in Rytary may look similar when scripted.	Orthographic: Hyflex contains an upstroke letter at the fourth position vs. Rytary does not contain an upstroke letter at the fourth position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Hyflex is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Hyflex.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
25	Epifoam (Hydrocortisone and Pramoxine) Foam Strength: hydrocortisone 1% and pramoxine 1% Dosage: Apply to affected area three to four times daily	Orthographic: The first letter 'r' and 'e' may look similar when scripted. Both names contain a down stroke letter at the second position and a cross stroke letter in the infix. Frequency of administration: Both products can be administered three or four times daily.	Orthographic: Rytary contains a down stroke letter 'y' in the suffix vs. Epifoam does not contain a down stroke letter in the suffix. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Epifoam is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Epifoam. Dosage: Rytary will be prescribed as "Take XX capsules" vs. Epifoam will be prescribed as "Apply XX amount."

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
26	Nystop (Nystatin) Powder Strength: 100,000 units per mL Dosage: Apply to affected area two to three times daily	Orthographic: The first letter 'r' and 'n' look similar when scripted. Both names contain a down stroke letter 'y' at the second position, a cross stroke letter 't' in the infix, and a down stroke letter in the suffix. Frequency of administration: Both products can be administered three times daily.	Orthographic: Nystop contains the letter 's' between the down stroke letter 'y' and the upstroke letter 't' vs. the down stroke letter 'y' is followed by the upstroke letter 't' in Rytary. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Nystop is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Nystop. Dosage: Rytary will be prescribed as "Take XX capsules" vs. Nystop will be prescribed as "Apply XX amount."

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
27	Zytiga (Abiraterone) Tablets Strength: 250 mg Dosage: 4 tablets by mouth once daily	Orthographic: The first letter 'r' and 'z' look similar when scripted. Both names contain a down stroke letter 'y' at the second position, a cross stroke letter 't' at the third position, and a down stroke letter in the infix.	Orthographic: Rytary contains two letters between the upstroke letter at the third position and the down stroke letter at the sixth position vs. Zytiga contains one letter between the upstroke letter at the third position and the down stroke letter at the fifth position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Zytiga is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Zytiga.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
28	Zuplenz (Ondansetron) Film Strength: 4 mg, 8 mg Dosage: 4 mg to 24 mg by mouth once to three times daily	Orthographic: The first letter 'r' and 'z' look similar when scripted. Both names contain a down stroke letter that is immediately followed by an upstroke letter. Additionally, both names can contain a down stroke letter at the last position. Frequency of administration: Both products can be administered three times daily	Strength: Both products have multiple strengths, which do not overlap and are not achievable.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
29	Dylix (dyphylline) Solution Strength: 100 mg per 15 mL oral solution Dosage: Up to 15 mg/kg/dose by mouth every 6 hours	Orthographic: The first letter 'D' and 'R' look similar when scripted, and both names contain the down stroke letter 'y' that is immediately followed by an upstroke letter. Dosage: A prescription for Dylix would be individualized based on the patient's weight, which could overlap with the dose for Rytary	Orthographic: Rytary contains two letters between the upstroke letter at the third position and the down stroke letter at the last position vs. Dylix contains one letter between the upstroke letter at the third position and the last position.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
30	Pylera (Bismuth Subcitrate Potassium, Metronidazole, and Tetracycline) Capsules Strength: bismuth subcitrate potassium 140 mg, metronidazole 125 mg, tetracycline 125 mg Dosage: 3 capsules by mouth four times daily	Orthographic: The first letter 'R' and 'P' look similar when scripted. Both names contain a down stroke letter 'y' that is immediately followed by an upstroke letter. The letter pair 'ar' in Rytary and 'er' in Pylera looks similar when scripted. Additionally, both names have six letters. Dosage: Both products can be written for 3 capsules by mouth four times daily.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Pylera does not contain a down stroke letter at the sixth position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Pylera is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Pylera.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
31	Raptiva (Efalizumab) Injection Strength: 125 mg powder solution for injection Dosage: 0.7 mg/kg subcutaneously, followed in one week with 1 mg/kg subcutaneously weekly	Orthographic: Both names begin with 'R' and contain a down stroke letter that is immediately followed by an upstroke 't.' Dosage: Although the dosage for Raptiva would be individualized to the patient's weight, the dosage of Raptiva could have potential to overlap with a strength of Rytary.	Orthographic: Raptiva contains one letter between the first letter 'R' and the down stroke 'p' vs. the first letter 'R' in Rytary is immediately followed by the down stroke 'y'. Rytary contains a down stroke letter 'y' at the sixth position vs. Raptiva does not contain a down stroke letter in the suffix. Frequency of administration: Rytary is administered three to five times daily vs. Raptiva is administered once weekly.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
32	Rotarix (rotavirus vaccine) Strength: G1P[8] $\geq 10^6$ $CCID_{50}$ per 1 mL powder for suspension Dosage: 1 mL by mouth at 2 months of age, then an additional 1 mL at age 4 months	Orthographic: Both names begin with 'R' and contain the letter string 'tar.' Phonetic: The second syllable of both names 'ta' is identical.	Orthographic: Rotarix does not contain any down stroke letters vs. Rytary contains a down stroke letter 'y' in the second position and sixth position. Phonetic: The first syllable of Rotarix 'ro' sounds different from the first syllable of Rytary 'ry.' Additionally, the 'x' in Rotarix has a distinct sound that differs from the pronunciation of Rytary. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Rotarix is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Rotarix.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
33	Rybix ODT (Tramadol) Disintegrating Tablet Strength: 50 mg Dosage: 50 mg to 100 mg by mouth every 4 to 6 hours as needed	Orthographic: Both names begin with 'Ry' and contain an upstroke letter immediately following the down stroke letter 'y,'	Orthographic: Rytary contains the upstroke letter 't' at the third position, which also provides a cross stroke letter. Additionally, Rytary contains two letters between the upstroke letter at the third position and the down stroke letter at the last position vs. Rybix ODT contains one letter between the upstroke letter at the third position and the letter at the last position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Rybix ODT is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Rybix ODT.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
34	Rynatan (chlorpheniramine, phenylephrine) chewable tablets and tablets; (azatadine, pseudoephedrine) extended-release tablets; (phenylephrine, pyrilamine, chlorpheniramine) Tablets Strength: chlorpheniramine 4.5 mg, phenylephrine 5 mg chewable tablet; chlorpheniramine 9 mg, phenylephrine 25 mg tablet; azatadine 1 mg, pseudoephedrine 120 mg extended-release tablet; phenylephrine 25 mg, pyrilamine 25 mg, chlorpheniramine 8 mg Dosage: ½ to 2 tablets by mouth every 12 hours	Orthographic: Both names begin with 'Ry' and contain an upstroke letter 't'. Additionally the letter pair 'ar' in Rytary looks similar to the letter pair 'an' in Rynatan. Phonetic: Both names have an identical first syllable of 'Ry.'	Orthographic: Since Rynatan contains 'na' in the infix, the position of the upstroke letter 't' in Rynatan is different from the position of the upstroke letter 't' in Rytary, giving Rynantan a different shape than Rytary. Additionally, the infix 'na' gives Rynatan a longer length than Rytary when scripted. Rytary contains a down stroke letter at the sixth position vs. Rynatan does not contain a down stroke letter in the suffix. Phonetic: The second and third syllable of Rynatan 'na' and 'tan' sound different than the second and third syllable of Rytary 'ta' and 'ry.' Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Rynatan is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Rynatan.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
35	Ry-Tann (chlorpheniramine and phenylephrine) Tablets Strength: chlorpheniramine 9 mg and phenylephrine 25 mg Dosage: 1 to 2 tablets by mouth every 12 hours	Orthographic: Although Ry-Tann includes a hyphen, this may be overlooked or written as one word. Both names begin with 'Ryta' and contain six letters.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Ry-Tann does not contain a down stroke letter at the sixth position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Ry-Tann is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Ry-Tann.
36	Rythmol (propafenone) Tablets Strength: 150 mg, 225 mg, 300 mg Dosage: 150 mg to 300 mg by mouth every 8 hours	Orthographic: Both names begin with 'Ryt'. Dosage: Both products can be prescribed as 1 by mouth every 8 hours	Orthographic: Rythmol contains two extra upstrokes at the fourth and seventh position, which gives it a distinct shape that differs from Rytary. Strength: Both products have multiple strengths, which do not overlap and are not achievable.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
37	Vytorin (ezetimibe and simvastatin) Tablets Strength: ezetimibe 10 mg, simvastatin 10 mg; ezetimibe 10 mg, simvastatin 20 mg; ezetimibe 10 mg, simvastatin 40 mg, ezetimibe 10 mg, simvastatin 80 mg Dosage: 1 tablet by mouth daily	Orthographic: The first letter 'V' in Vytorin and 'R' in Rytary look similar when scripted. Both names contain a down stroke letter 'y' that is immediately followed by an upstroke letter 't'. Additionally, the letter pair 'or' in Vytorin and 'ar' in Rytary look similar when scripted. Phonetic: This name was identified by an external study.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. vytorin does not contain a down stroke letter in the suffix. Phonetic: The three syllables in Vytorin sound different from the three syllables in Rytary. Strength: Both products have multiple strengths, which do not overlap and are not achievable.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
38	Pytest (Urea C-14) Strength: 1uCi Dosage: Use as directed	Orthographic: The first letter 'R' and 'P' look similar when scripted. Both names contain a down stroke letter 'y' at the second position that is immediately followed by an upstroke letter. Additionally, the letter strings 'es' in Pytest and 'ar' in Rytary look similar when scripted.	Orthographic: Rytary contains a down stroke letter at the sixth position vs. Pytest contains a cross stroke letter at the sixth position. Setting of Use: This product is used to diagnose H. pylori infections and is administered under a physician's supervision. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Pytest is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Pytest.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
39	Ry-Tuss (carbetapentane, chlorpheniramine, ephedrine, phenylephrine) Tablets and Suspension Strength: carbetapentane 60 mg, chlorpheniramine 5 mg, ephedrine 10 mg, phenylephrine 10 mg tablet; carbetapentane 30 mg, chlorpheniramine 4 mg, ephedrine 5 mg, phenylephrine 5 mg per 5 mL oral suspension Dosage: 1 to 2 tablets by mouth every 12 hours; 2.5 mL to 10 mL by mouth every 12 hours	Orthographic: Although Ry-Tuss includes a hyphen, this may be overlooked or written as one word. Both names begin with 'Ryt' and the letter pair 'ar' in Rytary and 'us' in Ry-Tuss look similar when scripted.	Orthographic: Rytary contains a down stroke letter at the sixth position vs. Ry-Tuss does not contain a down stroke letter at the sixth position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Ry-Tuss is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Ry-Tuss.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
40	Kytril (granisetron) Tablets and Injection Strength: 1 mg tablet; 2 mg per 10 mL oral solution; 0.1 mg per mL, 1 mg per mL, 4 mg per 4 mL solution for injection Dosage: 1 mg to 2 mg by mouth 60 minutes before chemotherapy or radiation; 10 mcg/kg intravenously 30 minutes before chemotherapy; 1 mg intravenous push before induction of anesthesia	Orthographic: The first letter 'R' and 'K' look similar when scripted. Both names contain a down stroke letter 'y' at the second position, an upstroke letter 't' at the third position, and have six letters.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Kytril contains an upstroke letter 'l' at the sixth position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Oral Kytril is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of oral Kytril.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
41	Butex Forte (acetaminophen, butalbital) Tablets Strength: acetaminophen 650 mg, butalbital 50 mg Dosage: 1 to 2 tablets by mouth every 4 hours as needed	Orthographic: The first and second letter 'Bu' and 'Ry' look similar when scripted and both names contain an upstroke 't' at the third position. Additionally, the letter pair 'ex' in Butex looks similar to 'ry' in Rytary when scripted.	Orthographic: Rytary contains two letters between the upstroke letter at the third position and the down stroke letter at the last position vs. Butex Forte contains one letter between the upstroke letter at the third position and the letter at the last position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Butex Forte is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Butex Forte.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
42	Dytan (diphenhydramine) Suspension Strength: 25 mg per 5 mL Dosage: 6.25 mg to 50 mg by mouth every 4 to 6 hours	Orthographic: The first letter 'D' and 'R' look similar when scripted, and both names contain the down stroke letter 'y' that is immediately followed by an upstroke letter 't'. Additionally, the letter string 'an' in Dytan and 'ar' in Rytary look similar when scripted.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Dytan does not contain a down stroke letter in the suffix. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Dytan is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Dytan.
43	Dytuss (diphenhydramine) Syrup Strength: 12.5 mg per 5 mL Dosage: 6.25 mg to 50 mg by mouth every 4 hours to 6 hours as needed	Orthographic: The first letter 'D' and 'R' look similar when scripted, and both names contain the down stroke letter 'y' that is immediately followed by an upstroke letter 't'. Additionally, the letter strings 'us' in Dytuss and 'ar' in Rytary look similar when scripted.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Dytuss does not contain a down stroke in the suffix Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Dytuss is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Dytuss.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
44	Lyteca (acetaminophen) Syrup Strength: 120 mg per 5 mL Dosage: 325 mg to 650 mg by mouth every 4 to 6 hours as needed; 10 mg/kg/dose to 15 mg/kg/dose every 4 to 6 hours as needed	Orthographic: The first letter 'l' and 'r' may look similar when scripted. Both names are six letters in length and contain a down stroke 'y' at the second position and an upstroke 't' at the third position. Additionally, the letter pair 'ec' in Lyteca looks similar to 'ar' in Rytary.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Lyteca does not contain a down stroke in the suffix Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Lyteca is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Lyteca.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
45	Nutrox (vitamin E, cysteine, ascorbic acid, niacinamide, taurine, glutathione, riboflavin, thiamine, calcium pantothenate, zinc oxide, vitamin A, selenium) Capsules Strength: vitamin E 150 international units, cysteine 60 mg, ascorbic acid 80 mg, niacinamide 50 mg, taurine 25 mg, glutathione 40 mg, riboflavin 25 mg, thiamine 25 mg, calcium pantothenate 22 mg, zinc oxide 15 mg, vitamin A 10,000 international units, selenium 75 mcg Dosage: 1 to 3 capsules by mouth with meals	Orthographic: The first letters 'nu' and 'ry' look similar when scripted, and both names contain the upstroke letter 't' at the third position. The sixth letter 'x' in Nutrox and 'y' in Rytary look similar when scripted. Dosage: Both products can be prescribed as 2 capsules by mouth three times daily	Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Nutrox is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Nutrox.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
46	Pylora (hyoscyamine, atropine, scopolamine, phenobarbital) Tablets Strength: hyoscyamine 0.1037 mg, atropine 0.0194 mg, scopolamine 0.0065 mg, phenobarbital 16.2 mg Dosage: 1 to 2 tablets by mouth 3 to 4 times daily	Orthographic: The first letter 'P' and 'R' look similar when scripted. Both names contain a down stroke letter 'y' with an upstroke letter immediately following the down stroke. The letter pair 'or' in Pylora and 'ar' in Rytary look similar when scripted. Additionally, both names have six letters. Dosage: Both products can be written for 2 by mouth three times daily.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Pylora does not contain a down stroke in the suffix Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Pylora is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Pylora.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
47	Pylori-Chek Breath Test (Urea C-13) Strength: 100 mg per vial Dosage: Use as directed	Orthographic: The first letter 'P' and 'R' look similar when scripted. Both names contain a down stroke letter 'y' at the second position that is immediately followed by an upstroke letter. Additionally, the letter pair 'or' in Pylori and 'ar' in Rytary look similar when scripted.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Pylori does not contain a down stroke in the suffix Setting of Use: This product is used to diagnose H. pylori infections and is administered under a physician's supervision. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Pylori is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Pylori.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
48	Reglan (metoclopramide) Tablets and Injection Strength: 5 mg, 10 mg tablet; 5 mg per mL solution for injection Dosage: 10 mg to 15 mg by mouth, intramuscularly, or intravenously up to four times daily; 10 mg intramuscularly, intravenously prior to the end of a surgical procedure; 1 mg/kg to 2 mg/kg intravenously 30 minutes prior to chemotherapy	Orthographic: Both names begin with 'R', contain a down stroke letter and an upstroke letter immediately following the down stroke letter, and have six letters. Additionally, the letter pair 'an' in Reglan looks similar to 'ar' in Rytary. Dosage: Both products can be prescribed as 1 by mouth four times daily.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Reglan does not contain a down stroke in the suffix Strength: Both products have multiple strengths, which would have to be specified on a prescription, and the strengths do not overlap and are not achievable.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
49	Rufen (ibuprofen) Tablets Strength: 600 mg Dosage: 1 tablet by mouth every 6 hours as needed	Orthographic: Both names begin with 'R' and contain an upstroke letter. The letter string 'uf' in Rufen and 'yt' in Rytary, and 'en' Rufen and 'ar' in Rytary look similar when scripted.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Rufen does not contain a down stroke in the suffix Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Rufen is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Rufen.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
50	Rulox (aluminum hydroxide, magnesium hydroxide) Suspension Strength: aluminum hydroxide 225 mg, magnesium hydroxide 200 mg per 5 mL Dosage: 5 mL to 50 mL by mouth every 3 to 6 hours	Orthographic: Both names begin with 'R' and contain an upstroke letter. The second letter 'u' in Rulox and 'y' in Rytary may look similar when scripted. Frequency of administration: Both products can be administered four times daily	Orthographic: Rytary contains two letters between the upstroke letter at the third position and the down stroke letter at the last position vs. Rulox contains one letter between the upstroke letter at the third position and the letter at the last position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Rulox is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Rulox.
51	Rutin (established name) Tablets Strength: 20 mg, 50 mg, 100 mg, 500 mg Dosage: 1 to 2 tablets by mouth daily	Orthographic: Both names begin with 'R', and contain an upstroke letter 't' at the third position. Additionally, the letter 'u' may look similar to a down stroke letter 'y'.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Rutin does not contain a down stroke in the suffix Strength: Both products have multiple strengths, and the strengths do not overlap and are not achievable.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
52	Ru-Tuss (belladonna alkaloids, chlorpheniramine, pseudoephedrine) Extended-release Tablets; (phenylephrine, chlorpheniramine) Liquid Strength: belladonna alkaloids 0.24 mg, chlorpheniramine 8 mg, pseudoephedrine 90 mg extended-release tablet; phenylephrine 5 mg and chlorpheniramine 2 mg per 5 mL oral liquid Dosage: 5 mL by mouth every 4 hours	Orthographic: Although Ru-Tuss includes a hyphen, this may be overlooked or written as one word. Both names begin with 'R' and contain an upstroke 't' at the third position. Additionally, the 'u' at the second position in Ru-Tuss and the 'y' at the second position in Rytary, and the letter pair 'us' in Ru-Tuss and 'ar' in Rytary look similar when scripted.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Ru-Tuss does not contain a down stroke in the suffix Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Ru-Tuss is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Ru-Tuss.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
53	Rydex (codeine, brompheniramine, pseudoephedrine) Liquid Strength: 6.3 mg codeine, 1.3 mg brompheniramine, 10 mg pseudoephedrine per 5 mL Dosage: 7.5 mL to 15 mL by mouth every 4 to 6 hours as needed	Orthographic: Both names begin with 'Ry' and contain an upstroke letter following the down stroke letter 'y' at the second position.	Orthographic: The upstroke letter 't' in Rytary at the third position also provides a cross stroke letter vs. Rydex does not contain a cross stroke letter at the third position. Additionally, Rytary contains two letters between the upstroke letter at the third position and the down stroke letter at the last position vs. Rydex contains one letter between the upstroke letter at the third position and the last position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Rydex is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Rydex.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
54	Vytone (hydrocortisone, iodoquinol) Cream Strength: hydrocortisone 1%, iodoquinol 1% Dosage: Apply to affected areas three to four times daily	Orthographic: The first letter 'v' and 'r' look similar when scripted. Both names contain the upstroke letter 'y' at the second position, which is immediately followed by an upstroke 't'. Additionally, the letter pair 'on' in Vytone and 'ar' in Rytary look similar when scripted	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Vytone does not contain a down stroke in the suffix Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Vytone is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Vytone. Dosage: Rytary will be prescribed as "Take XX capsules" vs. Vytone will be prescribed as "Apply XX amount"

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
55	Zylan (vitamin D, ascorbic acid, thiamine, riboflavin, pyridoxine, calcium pantothenate, nicotinamide, cyanocobalamin, vitamin A) Capsules Strength: vitamin D 400 international units, ascorbic acid 100 mg, thiamine 5 mg, riboflavin 5 mg, pyridoxine 2 mg, calcium patothenate 10 mg, nicotinamide 30 mg, cyanocobalamin 4 mcg, vitamin A 5,000 international units Dosage: Use as directed	Orthographic: The first letter 'z' and 'r' look similar when scripted. Both names contain the upstroke letter 'y' at the second position, which is immediately followed by an upstroke letter. Additionally, the letter pair 'an' in Zylan and 'ar' in Rytary look similar when scripted.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Zylan does not contain a down stroke in the suffix Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Zylan is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Zylan.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
56	Zylox (magnesium hydroxide, aluminum hydroxide) Suspension Strength: magnesium hydroxide 500 mg, aluminum hydroxide 500 mg per 5 mL Dosage: 10 mL to 20 mL by mouth four times daily	Orthographic: The first letter 'z' and 'r' look similar when scripted. Both names contain a down stroke letter 'y' at the second position, which is immediately followed by an upstroke letter. Frequency of administration: Both products can be administered four times daily	Orthographic: Rytary contains two letters between the upstroke letter at the third position and the down stroke letter at the last position vs. Zylox contains one letter between the upstroke letter at the third position and the last position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Zylox is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Zylox.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
57	Zytaze (zinc citrate and phytase) Capsules Strength: zinc citrate 25 mg, phytase 1,500 mg Dosage: 2 capsules by mouth daily for four days prior to and on the day of receiving botulinum toxin injections	Orthographic: The first letter 'z' and 'r' look similar when scripted. Both names contain the upstroke letter 'y' at the second position, which is immediately followed by the upstroke letter 't'. Additionally, the letter string 'az' in Zytaze and 'ar' in Rytary look similar when scripted.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Zytaze does not contain a down stroke at the sixth position. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Zytaze is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Zytaze.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary Dosage Form: Extended-release Capsules Strengths: carbidopa 23.75 mg and levodopa 95 mg; carbidopa 36.25 mg and levodopa 145 mg; carbidopa 48.75 mg and levodopa 195 mg; carbidopa 61.25 mg and levodopa 245 mg Usual Dose: (b) (4) three to five times daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
58			(b) (4)

*** This document contains proprietary and confidential information that should not be released to the public.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary Dosage Form: Extended-release Capsules Strengths: carbidopa 23.75 mg and levodopa 95 mg; carbidopa 36.25 mg and levodopa 145 mg; carbidopa 48.75 mg and levodopa 195 mg; carbidopa 61.25 mg and levodopa 245 mg Usual Dose: (b) (4) three to five times daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
59			(b) (4)

*** This document contains proprietary and confidential information that should not be released to the public.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
60	Dyline GG (dyphylline, guaifenesin) Solution and Tablets Strength: dyphylline 100 mg, guaifenesin 100 mg per 5 mL oral solution; dyphylline 200 mg, guaifenesin 200 mg tablet Dosage: 5 mL to 10 mL by mouth three to four times daily; ½ to 1 tablet by mouth three to four times daily; 4.4 mg/kg to 6.6 mg/kg of dyphylline in divided doses	Orthographic: The first letter 'D' and 'R' look similar when scripted. Both names contain a down stroke letter 'y' at the second position that is immediately followed by an upstroke letter at the third position. Dosage: Both products can be prescribed as 1 by mouth three times daily.	Orthographic: Rytary contains a down stroke letter 'y' at the sixth position vs. Dyline GG does not contain a down stroke in the suffix Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Dyline GG is a single strength and may be omitted on a prescription. The strengths of Rytary do not overlap and are not achievable with the strength of Dyline GG.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
61	Ritalin (methylphenidate) Strength: 5 mg, 10 mg, 20 mg tablet Dosage: 10 mg to 60 mg by mouth daily in two to three divided doses	Orthographic: Both names begin with 'R' and contain an upstroke letter 't' at the third position. Phonetic: The first and second syllable of Ritalin 'ri' and 'ta' and Rytary 'ry' and 'ta' sound similar when pronounced. Dosage: Both products are only available in one dosage form and can be prescribed as 1 or 2 by mouth three times daily	Orthographic: Ritalin does not contain any down stroke letters vs. Rytary contains a down stroke letter 'y' in the second and sixth position. Additionally, Ritalin contains an extra upstroke letter 'l' in the fifth position. Phonetic: The third syllable of Ritalin 'lin' sounds different than the third syllable of Rytary 'ry' Strength: Both products have multiple strengths, which would have to be specified on a prescription, and the strengths do not directly overlap.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
62	Ridaura (auranofin) Strength: 3 mg capsule Dosage: 3 mg by mouth two to three times daily or 6 mg by mouth daily	Phonetic: The first syllable 'Rid' in Ridaura and 'Ryt' in Rytary sound similar when pronounced. Dosage: Both products can be prescribed as one capsule by mouth three times daily.	Phonetic: The pronunciation of 'ra' in Ridaura and 'ry' in Rytary sound different. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Ridaura is a single strength and may be omitted on a prescription. The strengths of Rytary do not directly overlap with the strength of Ridaura.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
63	Reluri (phenylephrine, guaifenesin) Strength: phenylephrine 30 mg, guaifenesin 1,200 mg tablet Dosage: 2 to 4 tablets by mouth daily	Orthographic: Both names begin with 'R' and contain an upstroke letter at the third position. Additionally, both names contain six letters. Phonetic: The first syllable of both names 're' and 'ry' sound similar when pronounced and the third syllable of both names are identical 'ri.'	Orthographic: Reluri does not contain any down stroke letters vs. Rytary contains one down stroke letter 'y' in the second and sixth position. Phonetic: The second syllable of 'lu' in Reluri sounds different than the second syllable of 'ta' in Rytary. Strength: Rytary has multiple strengths, which would have to be specified on a prescription; Reluri is a single strength and may be omitted on a prescription. The strengths of Rytary do not directly overlap with the strength of Reluri.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Rytary **Dosage Form: Extended-release Capsules** **Strengths:** **carbidopa 23.75 mg and levodopa 95 mg;** **carbidopa 36.25 mg and levodopa 145 mg;** **carbidopa 48.75 mg and levodopa 195 mg;** **carbidopa 61.25 mg and levodopa 245 mg** **Usual Dose:** (b) (4) **three to five times daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
64	L. reuteri (lactobacillus) Strength: 100 million units chewable tablet Dosage: 1 tablet by mouth once daily	Phonetic: If the 'L' in L. reuteri were dropped, Reuteri and Rytary sound similar by beginning with 'R' and having three syllables. Additionally, the second and third syllable 'teri' and 'tary' sound similar when spoken.	Strength: Rytary has multiple strengths, which would have to be specified on a prescription; L. reuteri is a single strength and may be omitted on a prescription. The strengths of Rytary do not directly overlap with the strength of L. reuteri.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JULIE V NESHIEWAT
04/12/2012

IRENE Z CHAN
04/12/2012

KELLIE A TAYLOR
04/12/2012

CAROL A HOLQUIST
04/12/2012