

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

209661Orig1s000

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**

Date of This Review:	October 31, 2016
Application Type and Number:	NDA 209661
Product Name and Strength:	Bonjesta (doxylamine succinate and pyridoxine hydrochloride) extended-release tablet 20 mg/20 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Duchesnay
Panorama #:	2016-9896788
DMEPA Primary Reviewer:	Walter Fava, RPh., MSED.
DMEPA Acting Team Leader:	Lolita White, PharmD.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Bonjesta, 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 Bonjesta. The external study conducted by the (b) (4), is based on the proposed proprietary name Bonjesta (b) (4). The sponsor submitted the proposed name Bonjesta for our review, thus the results from the external study based on the proposed name Bonjesta (b) (4) are not included in this proprietary name review.

1.1 REGULATORY HISTORY

The Applicant currently markets Diclegis (doxylamine succinate and pyridoxine hydrochloride) delayed-release tablets, 10 mg/10 mg, for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management, under NDA 021876. Diclegis was approved on April 8, 2013, and the name was found acceptable in OSE Review #2012-1809, dated September 20, 2012. The Applicant has reformulated the drug product as an immediate release (10 mg doxylamine succinate/10 mg pyridoxine hydrochloride) + delayed release (10 mg doxylamine succinate/10 mg pyridoxine hydrochloride) for a total 20 mg doxylamine succinate and 20 mg pyridoxine hydrochloride per tablet, for the same indication. The new formulation has been submitted under a Prior Approval Supplement, NDA 021876/S-010.

To convey there is a different formulation for this drug product, the Applicant submitted the proposed proprietary name, Diclegis (b) (4)***, under another Prior Approval Supplement, NDA 021876/S-011, for review on October 8, 2015. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, Diclegis (b) (4)*** unacceptable from a safety perspective in OSE Review #2015-1710361, dated December 30, 2015.

The Applicant submitted the name, (b) (4)***, for review on May 25, 2016 which was found unacceptable in OSE Review RCM: 2016-8206243, dated August 23, 2016. The Applicant withdrew the name (b) (4)*** on August 26, 2016, and submitted the name Bonjesta for review under NDA 021876. Due to the change in product characteristics of the proposed doxylamine succinate and pyridoxine hydrochloride product, the submission was assigned a new NDA number (NDA 209661). Thus, in an email sent to the Applicant dated September 2, 2016, the Agency requested the request for proprietary name review for Bonjesta be resubmitted to NDA 209661.

The Applicant submitted the name Bonjesta, to NDA 209661 on September 9, 2016 for review.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 9, 2016 proprietary name submission.

	Diclegis	Bonjesta
Intended Pronunciation	dye kle' gis	bonn jest ah
Active Ingredient	Doxylamine succinate and	Doxylamine succinate and

	pyridoxine hydrochloride	pyridoxine hydrochloride
Indication of Use	Treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management	Treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management
Route of administration	Oral	Oral
Dosage Form	Delayed release tablets	(b) (4) extended release tablets
Strength	10 mg/10 mg	20 mg/20 mg (Immediate release (10 mg doxylamine succinate/10 mg pyridoxine HCl) + (b) (4) (10 mg doxylamine succinate/10 mg pyridoxine HCl) for a total of 20 mg doxylamine succinate and 20 mg pyridoxine HCl)
Dose and frequency	Take two tablets daily at bedtime. If symptoms are not adequately controlled, the dose can be increased to a maximum of four tablets daily (one in the morning, one mid-afternoon, and two at bedtime)	On day 1 take one tablet at bedtime. If this dose adequately controls symptoms the next day, continue taking one tablet daily at bedtime only. However, if symptoms persist on Day 2, take one tablet in the morning and one tablet at bedtime.
How supplied/container closure	Bottles of 100 tablets	Bottles of 100 tablets
Storage	Room temperature	Room temperature

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Bone, Reproductive, and Urologic Products (DBRUP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proprietary name^a.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Bonjesta in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 *FDA Name Simulation Studies*

Eighty-two practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, September 21, 2016 e-mail, the Division of Bone, Reproductive, and Urologic Products (DBRUP) 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 $\geq 50\%$ retrieved from our POCA search^b organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	4
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	222
Low similarity name pair: combined match percentage score $\leq 49\%$	0

^a USAN stem search conducted on (October 14, 2016).

^b POCA search conducted on (September 2, 2016) in version 3.2.

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

Our analysis of the 226 names contained in Table 1 and determined 225 names will not pose a risk for confusion as described in Appendices C through H. We note the proposed name could be confused with another proposed proprietary name currently under review, Benjorna*** (methylphenidate) (b) (4) capsules due to orthographic similarities and overlap in product characteristics. Benjorna is indicated for the treatment of (b) (4) Attention Deficit Hyperactivity Disorder (ADHD).

The orthographic similarity of this name pair stems from both names sharing the letters, 'B', 'n', 'j' and 'a', in the same positions in the names and having the same length (8 letters) and shape. The second letter, 'o' in Bonjesta may also look similar to the second letter, 'e' in Benjorna*** when scripted. Likewise, the fifth letter, 'e' in Bonjesta, may look similar to the fifth letter, 'o' in Benjorna*** when scripted. We note the proposed name Bonjesta contains an upstroke letter 't' in the seventh position, which is absent in Benjorna***. However, given the orthographic similarity of the rest of the name, this difference may be overlooked. Additionally, the letter 's' in the sixth position of Bonjesta may look similar to the letter 'r' in the sixth position of Benjorna*** when scripted. The orthographic similarity of this name pair is further supported by the FDA's Phonetic and Orthographic Computer Analysis (POCA) system which calculates a combined POCA score of 62% for this name pair and an orthographic only score of 66%, which suggests that the names have moderate similarity.

In addition to their orthographic similarities, this name pair also shares overlapping product characteristics. Both products are oral solid dosage forms (b) (4)

Despite the concerns for the potential for confusion between this name pair described above, we note that the application for Bonjesta has a PDUFA goal date of November 7, 2016, which precedes the action date for Benjorna***. Thus, we find Bonjesta conditionally acceptable at this time, and we will consider the potential for confusion between this name pair under the proprietary name review process for Benjorna***.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Bone, Reproductive, and Urologic Products (DBRUP) via e-mail on October 26, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DBRUP on October 27 2016, they stated no additional concerns with the proposed proprietary name, Bonjesta.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Shawnetta Jackson, OSE project manager, at 301-796-4952.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 9, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

APPEARS THIS WAY ON ORIGINAL

4 REFERENCES

1. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)

USAN Stems List contains all the recognized USAN stems.

2. *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.

3. *Electronic Drug Registration and Listing System (eDRLS) database*

The electronic Drug Registration and Listing System (eDRLS) was established to support the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. ^c

^c 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 49\%$.

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 $\geq 70\%$).

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.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 $\geq 50\%$ to $\leq 69\%$).

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
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	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: • 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. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • 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 <u>with</u> 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 <i>z</i> and <i>f</i>), 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 as vowel reduction, assimilation, or deletion? - Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 49\%$).

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. Bonjesta Study (Conducted on September 1, 2016)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Bonjesta 20mg/20mg one tablet po twice daily</i>	Bonjesta 20 mg/20 mg Take one by mouth twice daily #60
<u>Outpatient Prescription:</u> <i>Bonjesta 20mg/20mg + po twice daily #60</i>	

FDA Prescription Simulation Responses

309 People Received Study
82 People Responded

Study Name: Bonjesta

Total	27	27	28	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
BANJESTA	1	0	0	1
BONGESTA	0	12	0	12
BONJESHA	0	0	1	1
BONJESTA	12	10	27	49
BONJISTA	10	0	0	10
BONJITA	1	0	0	1
BONJUSTA	0	3	0	3
BONYISTA	1	0	0	1
BOYISTA	1	0	0	1
BPMJESTA	1	0	0	1
VANZESTA	0	1	0	1
VONGESTA	0	1	0	1

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

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a day	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Bonjesta	100	Proposed proprietary name that is the subject of this review.
2.	Bonjela	76	This is an international proprietary name available in the UK, Singapore, New Zealand, and Thailand.
3.	Benlysta	74	The infixes of this name pair ('-lys-' vs '-jes-') have sufficient orthographic differences. Bonjesta contains a down stroke letter 'j' in the fourth position whereas Benlysta contains the upstroke letter 'l' in the fourth position. This difference in the orthographic characteristics of the letters makes the shape of the word appear different when scripted. The onset of the second syllables sound different when spoken ('-jest-' vs '--list-') and have sufficient phonetic differences. When comparing product characteristics, Bonjesta is a multiple ingredient tablet available in one strength (20 mg/ 20 mg) that the patient self-administers by oral route. Benlysta is a powder for injection available in two strengths (120 mg and 400 mg) requiring reconstitution and infusion by a healthcare professional in an inpatient or clinic setting. Orders for Benlysta would require the prescriber to indicate a strength or dose and frequency and duration of infusion. It is not likely that a patient admitted to an inpatient setting already taking Bonjesta, would receive Benlysta in error considering the different product characteristics.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a day	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
4.	Congestac	70	The prefixes of this name pair ('Bon-' vs 'Con') have sufficient orthographic differences. The suffixes of the name pair '-a' vs 'ac', have sufficient orthographic differences. The onset of the sound of the first letters of this name pair ('-Buh-' vs 'Kuh-') of this name pair have sufficient phonetic differences. The pronunciation of the letter, 'B' at the beginning of Bonjesta is plosive and bilabial which requires articulation with both lips to produce the sound compared to pronunciation of the letter, 'C' which is fricative and palatal requiring the use the hard palate of the mouth to produce the sound. When comparing product characteristics, Bonjesta is a multiple ingredient tablet available in one strength (20 mg/ 20 mg) that the patient self-administers by oral route. Congestac (guaifenesin and pseudoephedrine) is also available in (b) (4) 400 mg/60 mg) and the strength needs to be included medication order , which will help to mitigate the risk of confusion between this name pair.

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

No.	Name	POCA Score (%)
1.	Bendeka	64
2.	(b) (4) ***	62

No.	Name	POCA Score (%)
3.	Bendopa	58
4.	Bosentan	58
5.	Boniva	56
6.	(b) (4) ***	55
7.	Spongia Tosta	55
8.	Belinostat	54
9.	Entresto	54
10.	Neulasta	54
11.	Prezista	54
12.	Pronestyl	54
13.	Duranest	52
14.	Binaca	50
15.	Blincyto	50
16.	Cenestin	50

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

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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.	Decongest	66	The prefixes ,infixes and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
2.	Fungistat	65	The prefixes and suffixes of this name pair have sufficient orthographic differences. The prefixes and suffixes of this name pair have sufficient phonetic differences.
3.	Bendectin	64	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
4.	Benoject-50	64	The suffixes of this name pair when comparing the root names (Bonjesta vs. Benoject) have sufficient orthographic differences . The second and third syllables of this name pair sound different when comparing the root names. The modifier “50” in the comparator name helps to differentiate this name pair, if included.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
5.	Congesta DM	64	The prefixes of this name pair when comparing the root names (Bonjesta vs. Congesta) have sufficient orthographic differences. The first syllables of this name pair when comparing the root names (Bonjesta vs. Congesta) sound different. The onset of the sound of the first letters of this name pair ('-Buh-' vs 'Kuh-') of this name pair have sufficient phonetic differences. The phonetic differences lie in the enunciation of the first letters of this name pair. The pronunciation of the letter, 'B' at the beginning of Bonjesta is plosive and bilabial which requires articulation with both lips to produce the sound compared to pronunciation of the letter, 'C' which is fricative and palatal requiring the use the hard palate of the mouth to produce the sound. The modifier "DM" in the comparator name helps to differentiate this name pair, if included.
6.	Congestant	64	The prefixes and suffixes of this name pair have sufficient orthographic differences. Congestant ends in the upstroke letter, 't' which is absent in Bonjesta. The first and third syllables of this name pair sound different.
7.	Fortesta	64	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second of this name pair sound different.
8.	Monistat	64	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
9.	Monistat 3	64	The prefixes, infixes, and suffixes of this name pair when comparing the root names (Bonjesta vs. Monistat) have sufficient orthographic differences. The first, second and third syllables of this name pair sound different when comparing the root names. The modifier “3” in the comparator name helps to differentiate this name pair, if included.
10.	Monistat 5	64	The prefixes, infixes, and suffixes of this name pair when comparing the root name (Bonjesta vs. Monistat) have sufficient orthographic differences. The first, second and third syllables of this name pair sound different when comparing the root names. The modifier “5” in the comparator name helps to differentiate this name pair, if included.
11.	Monistat 7	64	The prefixes, infixes, and suffixes of this name pair when comparing the root names (Bonjesta vs. Monistat) have sufficient orthographic differences. The first, second and third syllables of this name pair sound different when comparing the root names. The modifier “7” in the comparator name helps to differentiate this name pair, if included.
12.	Monistat-1	64	The prefixes, infixes, and suffixes of this name pair when comparing the root names (Bonjesta vs. Monistat) have sufficient orthographic differences. The first, second and third syllables of this name pair sound different when comparing the root names. The modifier “-1” in the comparator name helps to differentiate this name pair, if included.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
13.	Binosto	62	The infixes of this name pair have sufficient orthographic differences. Bonjesta contains the down stroke letter, ‘j’ in the fourth position which Binosto does not have. The second and third syllables sound different.
14.	Lunesta	62	The prefixes and infixes of this name pair have sufficient orthographic differences. . Bonjesta contains the down stroke letter, ‘j’ in the fourth position which Lunesta does not have. The first and second syllables of this name pair sound different.
15.	Pan-Mist LA	62	The infixes of this name pair when comparing the root names (Bonjesta vs Pan-Mist) have sufficient orthographic differences. The infixes of this name pair have sufficient phonetic differences when comparing the root names. The modifier “LA” in the comparator name helps to differentiate this name pair, if included. When comparing the name Bonjesta to the root name Pan-Mist, Bonjesta contains an extra syllable.
16.	Calgon Vesta	61	The prefixes and infixes of this name pair when comparing the root names (Bonjesta vs. Calgon) have sufficient orthographic differences. The first and second syllables of this name pair when comparing the root names sound different. The modifier “Vesta” in the comparator name helps to differentiate this name pair, if included.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
17.	Bar-Test	60	The infixes of this name pair have sufficient orthographic differences. The prefixes of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.
18.	Penject	60	The prefixes and suffixes of this name pair have sufficient orthographic differences. Bonjesta has an additional syllable which helps differentiate this name pair when spoken.
19.	Decongest-B	60	The prefixes and infixes of this name pair when comparing the root names (Bonjesta vs. Decongest) have sufficient orthographic differences. The first, second and third syllables of this name pair sound different when comparing the root names. The modifier “B” in the comparator name helps to differentiate this name pair, if included.
20.	Infestat	60	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables sound different when spoken.
21.	Solesta	60	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
22.	Pentostam	59	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
23.	Dymista	59	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
24.	Bacti-Stat	58	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
25.	Benahist-10	58	The infixes and suffixes of this name pair when comparing the root names (Bonjesta vs. Benahist) have sufficient orthographic differences. The second and third syllables of this name pair sound different when comparing the root names. The modifier “10” in the comparator name helps to differentiate this name pair, if included.
26.	Bentex	58	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.
27.	Brontex	58	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
28.	Novagest	58	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
29.	Benzefoam	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
30.	Betastat	56	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
31.	Bonikraft	56	The infixes and suffixes of this name pair have sufficient orthographic differences. Bonikraft has two consecutive upstroke letters, 'ft' at the end which Bonjesta does not have. The second and third syllables of this name pair sound different.
32.	Pentaspán	56	The infixes and suffixes of this name pair have sufficient orthographic differences. Pentaspán has the upstroke and down stroke letters, 't' and 'p' in different positions from the upstroke and down stroke letters, 'j' and 't' in Bonjesta. The second and third syllables of this name pair sound different.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
33.	Degest	56	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.
34.	Depotest	56	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
35.	Sudogest	56	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
36.	Twinject	56	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.
37.	Twinject 0.15	56	The prefixes and suffixes of this name pair when comparing the root names (Bonjesta vs. Twinject) have sufficient orthographic differences. The first and second syllables of this name pair sound different when comparing the root names. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken. The modifier “0.15” in the comparator name helps to differentiate this name pair, if included.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
38.	Twinject 0.3	56	The prefixes and suffixes of this name pair when comparing the root names (Bonjesta vs. Twinject) have sufficient orthographic differences. The first and second syllables of this name pair sound different when comparing the root names. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken. The modifier “0.3” in the comparator name helps to differentiate this name pair, if included
39.	Venastat	56	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
40.	Lunesta	55	The prefixes of this name pair have sufficient orthographic differences. Bonjesta contains the down stroke letter, ‘j’ in the fourth position which is absent in Lunesta. The prefixes of this name pair have sufficient phonetic differences. The
41.	Menorest 37.5	55	The prefixes, infixes, and suffixes of this name pair when comparing the root names (Bonjesta vs. Menorest) have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different when comparing the root names. The modifier “37.5” in the comparator name helps to differentiate this name pair, if included

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
42.	Menorest 50	55	The prefixes, infixes, and suffixes of this name pair when comparing the root names (Bonjesta vs. Menorest) have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different when comparing the root names. The modifier “50” in the comparator name helps to differentiate this name pair, if included
43.	Menorest 75	55	The prefixes, infixes, and suffixes of this name pair when comparing the root names (Bonjesta vs. Menorest) have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different when comparing the root names. The modifier “75” in the comparator name helps to differentiate this name pair, if included
44.	Pangestyme	55	The infixes, and suffixes of this name pair have sufficient orthographic differences. Pangestyme contains a down stroke letter, ‘y’ in the suffix which is absent in Bonjesta. The first and third syllables of this name pair sound different.
45.	Syntest	55	The prefixes and suffixes of this name pair have sufficient orthographic differences. Syntest contains a down stroke letter, ‘y’ in the second position which Bonjesta does not have. The first syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
46.	Bancap HC	54	The suffixes of this name pair, when comparing the root names (Bonjesta vs Bancap) have sufficient orthographic differences. The second syllables of this name pair sound different when comparing the root names. The modifier “HC” in the comparator name helps to differentiate this name pair, if included.
47.	Benerva	54	The infixes of this name pair have sufficient orthographic differences. Bonjesta contains the down stroke letter, ‘j’ and the upstroke letter, ‘t’ in the infix which are absent in Benerva. The second and third syllables of this name pair sound different.
48.	Benzodent	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
49.	Bidex-A	54	The prefixes and suffixes of this name pair when comparing the root names (Bonjesta vs. Bidex) have sufficient orthographic differences. The first and second syllables sound different when comparing the root names. The modifier “A” in the comparator name helps to differentiate this name pair, if included.
50.	Bioblast	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
51.	Biohist-LA	54	The prefixes, infixes, and suffixes of this name pair when comparing the root names (Bonjesta vs. Biohist) have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different when comparing the root names. The modifier “LA” in the comparator name helps to differentiate this name pair, if included.
52.	Bionect	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
53.	(b) (4) ***	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
54.	Aloe Vesta	54	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. Aloe Vesta contains an additional syllable which helps differentiate this name pair when spoken.
55.	Ancestim	54	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
56.	Carlesta	54	The prefixes and infixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different.
57.	Dermastat	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
58.	Menostar	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
59.	Natesto	54	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
60.	Perestan	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
61.	Progest	54	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.
62.	Vagistat	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
63.	Vagistat-1	54	The prefixes, infixes, and suffixes of this name pair when comparing root names (Bonjesta vs. Vagistat) have sufficient orthographic differences. The first, second and third syllables of this name pair sound different when comparing the root names. The modifier “-1” in the comparator name helps to differentiate this name pair, if included.
64.	Benekraft	53	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
65.	Benekraft-25	53	The infixes and suffixes of this name pair when comparing root names (Bonjesta vs. Benekraft) have sufficient orthographic differences. The second and third syllables of this name pair sound different when comparing the root names. The modifier “-25” in the comparator name helps to differentiate this name pair, if included.
66.	Benzacot	53	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
67.	Gynorest	53	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
68.	Menest	53	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.
69.	Monistat I.V.	53	The prefixes, infixes and suffixes of this name pair when comparing root names (Bonjesta vs. Monistat) have sufficient orthographic differences. The first, second and third syllables of this name pair sound different when comparing the root names. The modifier “I.V.” in the comparator name helps to differentiate this name pair, if included.
70.	Bentasil	53	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
71.	Benz-O-Sthetic	53	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. Benz-O-Sthetic contains an additional syllable which helps differentiate this name pair when spoken.
72.	Bevespi	52	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
73.	Bextra	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.
74.	Bidhist	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.
75.	Brom Tann PE	52	The prefixes and suffixes of this name pair when comparing the root names (Bonjesta vs. Brom Tann) have sufficient orthographic differences. The first and second syllables of this name pair sound different when comparing the root names. The modifier “PE” in the comparator name helps to differentiate this name pair, if included. .
76.	Bronkids	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
77.	Congestaid II	52	The prefixes and suffixes of this name pair when comparing the root names (Bonjesta vs Congestaid) have sufficient orthographic differences. The first and third syllables of this name pair sound different when comparing the root names . The modifier “DM” in the comparator name helps to differentiate this name pair, if included.
78.	Dermarest	52	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
79.	Genestin	52	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
80.	Levonest	52	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
81.	Oxistat	52	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
82.	Prednistab	52	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
83.	Pseudo-Gest	52	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
84.	Baclospas	51	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
85.	Balanta	51	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
86.	Banflex	51	The suffixes of this name pair have sufficient orthographic differences. The second syllable of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.
87.	Benzac AC	51	The suffixes of this name pair when comparing the root names (Bonjesta vs. Benzac) have sufficient orthographic differences. The second syllable of this name pair sound different when comparing the root names. When comparing the root names, Bonjesta contains an extra syllable. The modifier “DM” in the comparator name helps to differentiate this name pair, if included.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
88.	Benzashave	51	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
89.	Benzashave 10	51	The prefixes, infixes, and suffixes of this name pair when comparing the root names (Bonjesta vs. Benzashave) have sufficient orthographic differences. The second and third syllables of this name pair sound different when comparing root names. The modifier “10” in the comparator name helps to differentiate this name pair, if included.
90.	Benzashave 5	51	The prefixes, infixes, and suffixes of this name pair when comparing the root names (Bonjesta vs. Benzashave) have sufficient orthographic differences. The second and third syllables of this name pair sound different when comparing the root names. The modifier “5” in the comparator name helps to differentiate this name pair, if included.
91.	Benzepro	51	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
92.	Benziq LS	51	The suffixes of this name pair have when comparing the root names (Bonjesta vs. Benziq) sufficient orthographic differences. The second syllables of this name pair sound different when comparing the root names. The modifier “LS” in the comparator name helps to differentiate this name pair, if included..

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
93.	Bion Tears	51	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
94.	Nexesta Fe***	51	The prefixes, infixes, and suffixes of this name pair when comparing the root names (Bonjesta vs Nexesta) have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different when comparing the root names. The modifier “FE” in the comparator name helps to differentiate this name pair, if included..
95.	Bencort	50	The suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.
96.	Benzac	50	The suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.
97.	Benzac W	50	The suffixes of this name pair when comparing the root names (Bonjesta vs. Benzac) have sufficient orthographic differences. The second syllable of this name pair sound different when comparing the root names. The modifier “W” in the comparator name helps to differentiate this name pair, if included.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
98.	Body Essence	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. Body Essence contains an additional syllable which helps differentiate this name pair when spoken.
99.	Broda Acne Spa	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. Broda Acne Spa contains two additional syllables which helps differentiate this name pair when spoken.
100.	Canesten	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first third syllables of this name pair sound different.
101.	Clinistat	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
102.	Cortastat	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
103.	Cortastat 10	50	The prefixes, infixes, and suffixes of this name pair when comparing the root names (Bonjesta vs. Cortastat) have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different when comparing the root names. The modifier “10” in the comparator name helps to differentiate this name pair, if included.
104.	Decongestamine	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. Decongestamine contains two additional syllables which helps differentiate this name pair when spoken.
105.	Decongestant II	50	The prefixes, infixes, and suffixes of this name pair, when comparing the root names (Bonjesta vs Decongestant) have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different when comparing the root names. The modifier “II” in the comparator name helps to differentiate this name pair, if included.
106.	Decongestant-SR	50	The prefixes, infixes, and suffixes of this name pair, when comparing the root names (Bonjesta vs Decongestant) have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different when comparing the root names . The modifier “SR” in the comparator name helps to differentiate this name pair, if included.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
107.	Evista	50	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
108.	Femtest	50	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.
109.	Modrastane	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
110.	Pentastarch	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
111.	Sinustab	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

No.	Proposed name: Bonjesta Established name: doxylamine succinate and pyridoxine hydrochloride Dosage form: extended-release tablets Strength(s): 20 mg/20 mg Usual Dose: One tablet by mouth twice a 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
112.	Sudogest PE	50	The prefixes, infixes, and suffixes of this name pair when comparing the root names (Bonjesta vs Sudogest) have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different when comparing the root names. The modifier “PE” in the comparator name helps to differentiate this name pair, if included.
113.	Testa Span	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
114.	Thrombostat	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
115.	Twynsta	50	The prefixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different. Bonjesta contains an additional syllable which helps differentiate this name pair when spoken.

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

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.	Banex-LA	60	Product withdrawn from the market due to safety concerns.
2.	Dienogest	60	Not marketed in the US as a finished dosage form, it is only available in combination with ethinyl estradiol in the US.
3.	Benzyl PCA	58	This is not a drug. This is an ingredient found in cosmetics.
4.	Condegest	58	Product withdrawn from the market due to safety concerns
5.	(b) (4) ***	58	(b) (4)
6.	Benzie Pak	56	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
7.	Ponstan	56	International product marketed in Australia
8.	Tolrestat	56	International product marketed in Europe.
9.	De-Congestine	54	International product marketed in Switzerland
10.	(b) (4)		
11.	(b) (4)		
12.	Brondelate	52	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
13.	Bunazosin	51	International product marketed in Japan
14.	Propagest	50	Product withdrawn from the market due to safety concerns
15.	Benzoate	50	This is not a drug, it is a preservative in a variety of foods.
16.	(b) (4)		

No.	Name	POCA Score (%)	Failure preventions
17.	Polyester-10	50	This is not a drug. It is an ingredient in cosmetics.
18.	Polyester-7	50	This is not a drug. It is an ingredient in cosmetics.

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

No.	Name	POCA Score (%)
1.	Concerta	64
2.	Mononessa	60
3.	Venclexta	58
4.	Amjevita***	56
5.	Comhist La	56
6.	Nuedexta	56
7.	(b) (4) ***	56
8.	Oncaspar	55
9.	Concept Ob	54
10.	Darvocet A500	54
11.	Dawnmist	54
12.	Mono-Gesic	54
13.	Nohist A	54
14.	Oxecta	54
15.	Panmist	54
16.	Perjeta	54
17.	(b) (4) ***	54
18.	Santex La	54
19.	Vita-Respa	54
20.	(b) (4) ***	54
21.	Congess	53
22.	Gentex La	53
23.	Phentex La	53

No.	Name	POCA Score (%)
24.	Tradjenta	53
25.	(b) (4) ***	52
26.	Canges Hc	52
27.	Conex La	52
28.	Congess Sr	52
29.	(b) (4) ***	52
30.	Decongex-3	52
31.	Depoject-80	52
32.	Dolgesic	52
33.	Donnatal	52
34.	Fungisan	52
35.	Linhist-L.A.	52
36.	Monovisc	52
37.	Numfast	52
38.	Onzetra	52
39.	Ponderax	52
40.	Congess Jr.	51
41.	Conte-Pak-4	51
42.	Gen-Lanta	51
43.	Gingera	51
44.	Lantex-La	51
45.	Omniscan	51
46.	Zometa	51
47.	Antispas	50
48.	Candesartan	50
49.	Dramoject	50
50.	Entex La	50
51.	Gadovist***	50
52.	Gencept 10/11-21	50
53.	Gencept 10/11-28	50

No.	Name	POCA Score (%)
54.	Genexa	50
55.	Kenaject	50
56.	Kenaject-40	50
57.	Kronofed-A	50
58.	(b) (4) ***	50
59.	Ninjacof A	50
60.	Novafed A	50
61.	Omnihist L.A.	50
62.	Pentasa	50
63.	Pentetate	50
64.	Phenoject	50
65.	Phenoject-50	50
66.	Plan B One-Step	50
67.	Ponstel	50
68.	Sonahist	50
69.	Sonata	50
70.	Umecta	50
71.	Zinc-Dtpa	50

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

No.	Name
1.	n/a

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

/s/

WALTER L FAVA
10/31/2016

LOLITA G WHITE
10/31/2016