CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206302Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	March 23, 2016
Application Type and Number:	NDA 206302
Product Name and Strength:	Byvalson (nebivolol/valsartan) Tablets, 5 mg/80 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Forest Laboratories, LLC
Panorama #:	2015-1601732
DMEPA Primary Reviewer:	Sarah Thomas, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Reference ID: 3906778

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1 INTRODUCTION

The purpose of this memorandum is to reassess the proposed proprietary name "Byvalson" under NDA 206302 in response to a change in tablet strength [redacted] (b) (4) to 5 mg/80 mg of nebivolol/valsartan.

1.1 Regulatory History

The Applicant previously submitted the proposed proprietary name Byvalson on June 12, 2014. The Division of Medication Error Prevention and Analysis (DMEPA) evaluated the name based on several proposed fixed-dose combination strengths: 5 mg/80 mg, 5 mg/160 mg, 10 mg/160 mg, 10 mg/320 mg, and 20 mg/320 mg. DMEPA found the name Byvalson acceptable in OSE Review #2014-25586, dated August 12, 2014.[1] However, the application received a Complete Response on December 24, 2014.

On September 30, 2015, as a part of the resubmission for NDA 206302, the Applicant resubmitted the name Byvalson for review based on a single fixed-dose combination strength [redacted] (b) (4). DMEPA found the name Byvalson acceptable in OSE Review #2015-1601732, dated December 21, 2015.[2]

2 METHODS AND DISCUSSION

For reassessment of the proposed proprietary name, we evaluated previous proprietary name reviews dated December 21, 2015 and August 12, 2014 to assess whether the change in strength would alter our previous conclusions regarding the acceptability of the proposed proprietary name.

We evaluated the results of our previous POCA search in OSE review # 2015-1601732[2] to identify names with overlapping strength and/or dose with the new 5 mg/80 mg strength.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The March 22, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Our evaluation of previous POCA search results[2] and USAN stem did not identify any new names that represent a potential source of drug name confusion. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. As a result, we maintain that the name is acceptable.

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[1] Olumba, J. Proprietary Name Review for Byvalson (NDA 206302). 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); 2014 AUG 12. OSE RCM No.: 2014-25586.

[2] Stewart, J. Proprietary Name Review for Byvalson (NDA 206302). 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); 2015 DEC 21. OSE RCM No.: 2015-1601732.

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3 CONCLUSION

The proposed proprietary name, Byvalson, is acceptable from both a misbranding and safety perspective under NDA 206302.

If you have further questions or need clarifications, please contact Darrell Lyons, OSE project manager at 301-796-4092.

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/s/

SARAH E THOMAS
03/23/2016

CHI-MING TU
03/23/2016

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)

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Date of This Review:	December 21, 2015
Application Type and Number:	NDA 206302
Product Name and Strength:	Byvalson (nebivolol/valsartan) Tablets, (b) (4)
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Forest Laboratories, LLC
Panorama #:	2015-1601732
DMEPA Primary Reviewer:	Janine Stewart, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Byvalson, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by [redacted] (b) (4) for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name Byvalson on June 12, 2014. The Division of Medication Error Prevention and Analysis (DMEPA) evaluated the name based several proposed fixed-dose combination strengths: 5 mg/80 mg, 5 mg/160 mg, 10 mg/160 mg, 10 mg/320 mg, and 20 mg/320 mg. DMEPA found the name Byvalson acceptable in OSE Review #2014-25586, dated August 12, 2014. However, the application received a Complete Response on December 24, 2014.

On September 30, 2015, as part of the resubmission for NDA 206302, the Applicant resubmitted the name Byvalson for review based on a single fixed-dose combination strength [redacted] (b) (4)

1.2 PRODUCT INFORMATION

The following product information is provided in the September 30, 2015 proprietary name submission.

- Intended Pronunciation: bye- VAL-son
- Active Ingredient: nebivolol/valsartan
- Indication of Use: For the treatment of hypertension.
- Route of Administration: Oral
- Dosage Form: Tablet
- Strength: [redacted] (b) (4)
- Dose and Frequency: One tablet daily.
- How Supplied: 30 and 90 count bottles
- Storage: Store at 20° to 25°C (68° to 77°F) [see USP for Controlled Room Temperature]
- Container and Closure Systems: [redacted] (b) (4) high density polyethylene (HDPE) bottles [redacted] (b) (4)

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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 Cardiovascular and Renal Products (DCRP) 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[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Byvalson, was derived from a "fixed dose combination of **By**stolic and **Val**sartan. 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. While the proposed name suggests Bystolic (nebivolol) and valsartan, we do not object to Byvalson in this case because it does suggest all and both active ingredients.

2.2.3 FDA Name Simulation Studies

Sixty-eight practitioners participated in DMEPA's prescription studies. Thirty-three (33) participants correctly interpreted the proposed name as Byvalson. Common misinterpretations include misinterpreting the first syllable "By" as "Bi" (n=18), and the last syllable "son" as "sin" (n=10) in the voice study. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 8, 2015 e-mail, the Division of Cardiovascular and Renal Products (DCRP) 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[2] organized as highly similar, moderately similar,

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[1]USAN stem search conducted on October 8, 2015.

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or low similarity for further evaluation. Table 1 also includes names identified by (b) (4)

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%	157
Low similarity name pair: combined match percentage score ≤49%	3

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

Our analysis of the 161 names contained in Table 1 determined none of the names would 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 Cardiovascular and Renal Products (DCRP) via e-mail on December 18, 2015. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DCRP on December 21, 2015, they stated no additional concerns with the proposed proprietary name, Byvalson.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Darrell Lyons, OSE project manager, at 301-796-4092.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 30, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[2] POCA search conducted on November 4, 2015.

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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 supports 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. [3]

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

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***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 checklist (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.

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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.

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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?		

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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: • 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 **with** overlapping or similar strengths or doses.

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	Orthographic Checklist (Y/N to each question)	Phonetic 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?	• 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.

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Appendix B: Prescription Simulation Samples and Results

Figure 1. Byvalson Study (Conducted on November 6, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Byvalson 5mg/80mg 1 tablet po once daily Outpatient Prescription: Patient _____ Date 11/6/15 Address _____ ℞ Byvalson [redacted] (b) (4) Take 1 tab po q day Disp 90 MEDWATCH 1-800-FDA-1088 Refill(s): _____ Dr. OSE DEA No. _____ Address _____ Telephone _____	Byvalson [redacted] (b) (4) Take 1 tablet by mouth once daily. Dispense: 90

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)
Study Name: Byvalson

242 people received study

68 people responded

Study Name: Byvalson

Total	25	19	24	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
BIVALCIN	0	2	0	2
BIVALICEN	0	1	0	1
BIVALSEN	0	3	0	3
BIVALSIN	0	9	0	9
BIVALSYN	0	1	0	1
BIVELCIN	0	1	0	1
BIVELSIN	0	1	0	1
BYBVOLEON	1	0	0	1
BYOVALSAN	0	0	1	1
BYVALAON	5	0	0	5
BYVALCIN	0	1	0	1
BYVALEON	3	0	0	3
BYVALOAN	1	0	0	1
BYVALSAN	0	0	2	2
BYVALSOM	0	0	2	2
BYVALSON	14	0	19	33
BYVOLEON	1	0	0	1

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

No.	**Proposed name:** Byvalson **Established name:** Nebivolol/Valsartan **Dosage form:** Oral Tablet **Strength(s):** (b) (4) **Usual Dose:** 1 tablet daily	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Byvalson	100	This proprietary name is the 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.	BELDIN	55
2.	BENYLIN	54
3.	BEPADIN	50
4.	BIAXIN	51
5.	BICILLIN	56
6.	BOSENTAN	53
7.	BUTALAN	60
8.	DRALSERP	54
9.	EQVALAN	52
10.	MIDOL TEEN	52
11.	MYCASONE	52
12.	PYRIL TANN-12	58
13.	VALERGEN	50
14.	VALISONE	58
15.	VIBISONE	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:** Byvalson **Established name:** Nebivolol/Valsartan **Dosage form:** Oral Tablet **Strength(s):** (b) (4) **Usual Dose:** 1 tablet daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	BACLOFEN	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
2.	BALAGAN	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The second, and third syllables of this name pair sound different.
3.	BALGIFEN	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
4.	BALTUSSIN	54	The prefixes and infixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different.
5.	BANOPHEN	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.
6.	BAYCADRON	54	The prefixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

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No.	**Proposed name:** Byvalson **Established name:** Nebivolol/Valsartan **Dosage form:** Oral Tablet **Strength(s):** (b) (4) **Usual Dose:** 1 tablet daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
7.	BEBULIN	58	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
8.	BEE POLLEN	54	The prefixes and infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
9.	BELSOMRA ***	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.
10.	BENZACLIN	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.
11.	BETALIN	60	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.
12.	BETALIN 12	61	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. The name Betalin 12 contains an extra syllable.

No.	**Proposed name:** Byvalson **Established name:** Nebivolol/Valsartan **Dosage form:** Oral Tablet **Strength(s):** (b) (4) **Usual Dose:** 1 tablet daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
13.	BETALIN S	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. The name Betalin S contains an extra syllable.
14.	BETASERON	52	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. The name Betaseron contains an extra syllable.
15.	BICARSIM	53	The prefixes and infixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different.
16.	BIOLON	57	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
17.	BIVALIRUDIN	55	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different. The name Bivalirudin contains two extra syllables.
18.	BREVICON	58	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

No.	**Proposed name:** Byvalson **Established name:** Nebivolol/Valsartan **Dosage form:** Oral Tablet **Strength(s):** (b) (4) **Usual Dose:** 1 tablet daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
19.	BUCALCIDE	50	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
20.	BUCALSEP	58	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
21.	BUSULFAN	62	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
22.	BYDUREON	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. The name Bydureon has an extra syllable.
23.	CARLSON D	54	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
24.	CODELSON	62	The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.

No.	**Proposed name:** Byvalson **Established name:** Nebivolol/Valsartan **Dosage form:** Oral Tablet **Strength(s):** (b) (4) **Usual Dose:** 1 tablet daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
25.	DAMASON-P	54	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. The name Damason-P contains an extra syllable.
26.	DISALCID	54	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
27.	TOVALT ODT	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different. The name Tovalt ODT contains two additional syllables.
28.	TYVASO	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.
29.	VALSARTAN	58	The prefixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
30.	VALTROPIN	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

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No.	**Proposed name:** Byvalson **Established name:** Nebivolol/Valsartan **Dosage form:** Oral Tablet **Strength(s):** (b) (4) **Usual Dose:** 1 tablet daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
31.	VYVANSE	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
32.	ZEVALIN	60	The prefixes and suffixes 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.	BYSTOLIC	44
2.	LYSODREN	41
3.	RYNATAN	46

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-12 RESIN	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
2.	BAICALEIN	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database. A flavone constituent of the skullcap plant.
3.	BAICALIN	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database. A flavone constituent of the skullcap plant.
4.	BELLALPHEN	66	Name identified in RxNorm database. RedBook database indicated this product as discontinued on 10/05/1993 with no generic equivalent.
5.	BETADREN	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
6.	BETA-ESCIN	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

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No.	Name	POCA Score (%)	Failure preventions
7.	BETAFERON	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
8.	BETALOC	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
9.	BETAXON	61	Name identified in Drugs @FDA database. This is a discontinued product with no generic equivalent available.
10.	BETNELAN	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
11.	BILOPTIN	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
12.	BIO-D-MULSION	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
13.	BISOLVINE	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

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No.	Name	POCA Score (%)	Failure preventions
14.	BISOLVON	69	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database. Foreign drug name in Europe, South America, and Asia.
15.	BORATE ION	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
16.	BOVADINE	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
17.	(b) (4) ***	60	Name identified in Names Entered by SE database. Name denied under OSE RCM# 2105-1210669 and 2015-12107671 for BLA 761042.
18.	BUNAZOSIN	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
19.	BUTASONE	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
20.	CARBARSON	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

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No.	Name	POCA Score (%)	Failure preventions
21.	LEVALLORPHAN	51	Name identified in RxNorm database. This product was marketed under the name Lorfan. Drugs @FDA database indicated this is a discontinued product with no generic equivalent. Withdrawn FR Effective 09/17/2001.
22.	MAOSON	50	Name identified in RxNorm database. RedBook database indicated this product as discontinued on 06/01/1996 with no generic equivalent.
23.	MESULFEN	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
24.	TEGISON	50	Name identified in Drugs @FDA database. This is a discontinued product with no generic equivalent available. Withdrawn FR Effective 09/10/2003.
25.	TYLVALOSIN	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
26.	VALBAZEN	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
27.	VALPIN 50	57	Name identified in Drugs @FDA database. This is a discontinued product with no generic equivalent available. Withdrawn FR Effective Status 08/20/2010.

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No.	Name	POCA Score (%)	Failure preventions
28.	VALTRUM	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
29.	VALU-FOAM	50	Name identified in RxNorm database. RedBook database indicated this product as discontinued on 12/17/1997 with no generic equivalent.
30.	VIVALAN	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
31.	(b) (4) ***	51	Name identified in Names Entered by SE database. Name denied under OSE RCM# 2013-1327 for NDA 203684. The product was approved under the name Lumason in ODE RCM# 2013-2105

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

No.	Name	POCA Score (%)
1.	ALBALON	50
2.	CALPHRON	52
3.	(b) (4) ***	54
4.	CHYMAR-ZON	52
5.	CIBACALCIN	51
6.	CYTACON	50
7.	DALALONE	54
8.	DALGAN	52
9.	DARVON	51
10.	DELALUTIN	54
11.	DELAXIN	50
12.	DELFEN	52
13.	DELTALIN	51
14.	DEPACON	54
15.	DERMALZONE	50
16.	DESOXYN	50
17.	DEXACEN-4	51
18.	DIFLUCAN	50
19.	DIGISAN	52
20.	DRALZINE	56
21.	DUPHASTON	56
22.	DURA RON	50
23.	DURACLON	55
24.	DURALONE	51
25.	DURALUTIN	54
26.	DURATION	51
27.	DUVADILAN	52
28.	DYNACIN	61

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No.	Name	POCA Score (%)
29.	DYNAPEN	56
30.	DYNAXIN	58
31.	DYPHYLLINE	51
32.	DYPHYSIN	56
33.	FIBERCON	52
34.	GAVILYTE-N	54
35.	GAVISCON	54
36.	GENATON	50
37.	MAXOLON	50
38.	MIACALCIN	51
39.	MIVACRON	56
40.	MOBILAN	50
41.	MYGDALON	61
42.	MYLAXEN	50
43.	MYSOLINE	50
44.	NALFON	59
45.	NAVELBINE	50
46.	NOVOLIN	52
47.	NOVOLIN 70/30	52
48.	NOVOLIN N	50
49.	PALPEON	52
50.	PATHILON	52
51.	PAVAGEN	50
52.	PAVULON	58
53.	PROBALAN	50
54.	SARALASIN	50
55.	SEBULON	53
56.	SELSUN	56
57.	SYLATRON	50
58.	SYNALAR N	53

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No.	Name	POCA Score (%)
59.	TESSALON	54
60.	TIADILON	50
61.	TOBRALCON	60
62.	TRILAFON	51
63.	TYLEFON	52
64.	VANACON	52
65.	VASATEN	53
66.	VASELINE	50
67.	VASOCON	54
68.	VELBAN	52
69.	VELTIN	54
70.	VERELAN	51
71.	VETASAN	52
72.	VICETON	52
73.	VIRILON	56
74.	VISTACON	51
75.	VIVARIN	50
76.	WAL-SOM	52
77.	ZALEPLON	52
78.	ZONALON	53
79.	ZYDACLIN	52

Reference ID: 3863537

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/s/

JANINE A STEWART
12/21/2015

CHI-MING TU
12/21/2015

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	August 12, 2014
Application Type and Number:	NDA 206302
Product Name and Strength:	Byvalson (Nebivolol/Valsartan) Tablets 5 mg/80 mg, 5 mg/160 mg, 10 mg/160 mg, 10 mg/320mg, and 20 mg/320 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	RX
Applicant/Sponsor Name:	Forest laboratories, Inc.
Submission Date:	June 12, 2014
Panorama #:	2014-25586
DMEPA Primary Reviewer:	Jean Olumba, MD, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Byvalson (Nebivolol/Valsartan), 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. The Applicant submitted an external name study, conducted by [redacted] (b) (4) for this product.

1.1 REGULATORY HISTORY

The sponsor previously submitted the proposed proprietary name, [redacted] (b) (4) on Feburary 26, 2014. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, [redacted] (b) (4) acceptable in OSE Review # 2014-17006 (DARRTS NDA 206302 Proprietary name review dated 3/20/2014).

Thus, the sponsor submitted the proposed proprietary name, Byvalson, for review on June 12, 2014; and listed [redacted] (b) (4) as an alternate proposed proprietary name.

1.2 PRODUCT INFORMATION

The following product information is provided in the June 12, 2014 proprietary name submission.

- Intended Pronunciation: bye-VAL-son
- Active Ingredient: nebivolol and valsartan
- Indication of Use: Treatment of hypertension
- Route of Administration: oral
- Dosage Form: Tablet
- Strength: 5 mg/80mg, 5 mg/160mg, 10mg/160mg, 10mg/320mg, 20mg/320 mg
- Dose and Frequency: One tablet daily [redacted] (b) (4)
- How Supplied: 30 and 90 count bottles [redacted] (b) (4)
- Storage: 20 to 25 degrees Celsius

2 RESULTS

The following sections provide information obtained and considered in the overall 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 Cardiovascular and Renal Products (DCRP) concurred with the findings of OPDP's promotional assessment of the proposed name.

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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[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Byvalson, was derived from a "fixed dose combination of **By**stolic and **Val**sartan. 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

One hundred (n=100) 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. 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, July 02, 2014 e-mail, the Division of Cardiovascular and Renal Products (DCRP) 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 organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified by (b) (4)

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%	165
Low similarity name pair: combined match percentage score ≤49%	3

[1]USAN stem search conducted on June 23, 2014

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

Our analysis of the 169 names contained in Table 1 determined 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 Cardiovascular and Renal Products (DCRP) via e-mail on July 23, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DCRP on July 30, 2014, they stated no additional concerns with the proposed proprietary name, Byvalson.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Cherye Milburn, OSE project manager, at 301-796-2084.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your June 12, 2014 submission are altered, the name must be resubmitted for review.

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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.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name.

1. **Promotional Assessment**: For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE 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 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. [2]

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

	Affirmative answers to these questions indicate a potential area of concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other Names?
Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

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

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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. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (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, 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 (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will review these 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 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 (See Table 5).

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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.

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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 these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair do not share a common strength or dose (see Step 1 of the Moderately Similar Checklist).			
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?		

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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 have a higher potential for confusion and should be evaluated further (see Step 2). For single strength products, also consider circumstances where the strength may not be expressed. For any combination drug products, 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 these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between moderately similar names **with** overlapping or similar strengths or doses.

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	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?

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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 there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product 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.

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Appendix B: Prescription Simulation Samples and Results

Figure 1. Byvalson Study (Conducted on June 26, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Byvalson 5/80 T tab po daily	Byvalson (b) (4) Take one tablet daily Dispense # 30
Outpatient Prescription: (b) (4)	

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FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

study name: byvalson

as of date 7/14/2014

265 people received study

100 people responded

study name: byvalson

total	38	28	34	
interpretation	**outpatient**	**voice**	**inpatient**	**total**
bimalson (b) (4)	0	1	0	1
bivalciin	0	1	0	1
bivalcin	0	3	0	3
bivalcin (b) (4)	0	1	0	1
bivalcine	0	1	0	1
bivalcintin	0	1	0	1
bivalfin	0	1	0	1
bivalsen	0	1	0	1
bivalsend	0	1	0	1
bivalsin	0	7	0	7
bivalveson	0	1	0	1
bivalvsin	0	2	0	2
bivalvsin (b) (4)	0	1	0	1
bivavlsen	0	1	0	1
brynalson (b) (4)	1	0	0	1
bryvalson	5	0	0	5
bryvalson (b) (4)	1	0	0	1

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bryvalson (b) (4)	1	0	0	1
buvalson (b) (4)	1	0	0	1
byualson	1	0	0	1
byualson (b) (4)	1	0	0	1
byulason	1	0	0	1
byvalsair	0	0	1	1
byvalsan	0	0	1	1
byvalsen	0	0	1	1
byvalsia	0	0	1	1
byvalsin	0	0	1	1
byvalsom	0	0	1	1
byvalson	22	0	19	41
byvalson 05/8	0	0	1	1
byvalson (b) (4)	4	0	0	4
byvalson 5/80	0	0	8	8
byvalstin	0	1	0	1
vivalcid	0	1	0	1
vivalset	0	1	0	1
vyvalsin	0	1	0	1
vyvalson	0	1	0	1

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

No.	**Proposed name:** Byvalson (nebivolol and valsartan) **Strength(s):** 5 mg/80mg, 5 mg/160mg, 10mg/160mg, 10mg/320mg, 20mg/320 mg **Usual Dose:** One tablet by mouth daily (b) (4)	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.	Byvalson	100	This is the proprietary name under this review

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

No.	Proposed Name	POCA Score (%)
1.	Busulfan	62
2.	BETAXON	61
3.	ZEVALIN	60
4.	Bebulin	58
5.	Bucalsep	58
6.	BICILLIN	56
7.	Bisolvine	56
8.	BIVALIRUDIN	55
9.	BYDUREON	54
10.	TYVASO	54
11.	BETASERON	52
12.	BIAXIN	51
13.	(b) (4) ***	51
14.	Bucalcide	50
15.	VIBISONE	50

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

No.	**Proposed name:** Byvalson (nebivolol and valsartan) **Strength(s):** 5 mg/80mg, 5 mg/160mg, 10mg/160mg, 10mg/320mg, 20mg/320 mg **Usual Dose:** One tablet by mouth daily (b) (4)	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.	BACLOFEN	54	The prefix and infix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
2.	Baltussin	54	The prefix and infix of this name pair has sufficient orthographic differences. The second syllable of this name pair sounds different.
3.	Banophen	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
4.	Baycadron	54	The second and third syllables of this name pair sound different. Byvalson is available in multiple non-overlapping strengths where a specific strength is needed on a prescription for dispensing, thus providing product characteristic differences.
5.	Bee pollen	54	The prefix and infix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
6.	BELDIN	55	The prefix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair sounds different. Byvalson*** has an extra syllable.

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No.	**Proposed name:** Byvalson (nebivolol and valsartan) **Strength(s):** 5 mg/80mg, 5 mg/160mg, 10mg/160mg, 10mg/160mg, 10mg/320mg, 20mg/320 mg **Usual Dose:** One tablet by mouth daily (b) (4)	**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**
7.	(b) (4)***	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
8.	Belsomra***	56	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
9.	(b) (4)***	50	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
10.	BENYLIN	54	The prefix and infix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
11.	BENZACLIN	53	The prefix and infix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
12.	BETALIN 12	61	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
13.	BETALIN S	54	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
14.	Bicarsim	53	The prefix and infix of this name pair have sufficient orthographic differences. The second syllable of this name pair sounds different.

No.	**Proposed name:** Byvalson (nebivolol and valsartan) **Strength(s):** 5 mg/80mg, 5 mg/160mg, 10mg/160mg, 10mg/320mg, 20mg/320 mg **Usual Dose:** One tablet by mouth daily (b) (4)	**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**
15.	Bosentan***	53	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. NDA 21290 OSE# 2010-179 was approved on 11/20/2001 under the name Tracleer. Bosentan*** is estasblished name.
16.	Brevicon	58	The prefix and infix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
17.	Carlson D	54	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
18.	Damason-P	54	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
19.	Mycasone	52	The infix of this name pair has sufficient orthographic differences. The first and second syllables of this name pair sound different.
20.	Valergen	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
21.	VALISONE	58	The prefix and infix of this name pair have sufficient orthographic differences. The second syllable of this name pair sounds different.

No.	**Proposed name:** Byvalson (nebivolol and valsartan) **Strength(s):** 5 mg/80mg, 5 mg/160mg, 10mg/160mg, 10mg/320mg, 20mg/320 mg **Usual Dose:** One tablet by mouth daily (b) (4)	**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**
22.	VALSARTAN	58	The prefix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different.
23.	VALTROPIN	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
24.	VYVANSE	50	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
1.	Bystolic	44
2.	Lysodern	36
3.	Rynatan	46

Appendix G: Names with unidentified product characteristics

No.	Name	POCA Score (%)	Failure preventions
1.	B-12 Resin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
2.	baicalin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
3.	Balagan	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
4.	Balgifen	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
5.	Bellalphen	66	Name identified in RxNorm database. RedBook database indicated this product as discontinued on 10/05/1993 with no generic equivalent.
6.	BEPADIN	50	Name identified in Drugs @FDA database. This is a discontinued product with no generic equivalent available. Withdrawn pending FR Notice 08/17/2005
7.	Betadren	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
8.	beta-Escin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
9.	Betaferon	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
10.	Betaloc	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

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No.	Name	POCA Score (%)	Failure preventions
11.	Betatan	54	Name identified in RxNorm database. RedBook database indicated this product as discontinued on 12/31/2006 with no generic eqivalent.
12.	Betnelan	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
13.	Biloptin	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
14.	Bio-D-Mulsion	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
15.	Biolon	57	Name identified in RxNorm database. RedBook database indicated this product as discontinued on 10/25/2005 with no generic equivalent.
16.	Bisolvon	69	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database. Foreign drug name in Europe, South America and Asia.
17.	BORATE ION	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
18.	Bovadine	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
19.	bunazosin	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
20.	BUTALAN	60	Drugs @FDA database indicated this is a discontinued product with no generic equivalents.

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No.	Name	POCA Score (%)	Failure preventions
21.	Butasone	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
22.	(b) (4)***	50	Name identified in Names Entered by SE database. NDA 22052 OSE # 2006-809 was approved on 05/30/2007 under the name Zyflo XR
23.	Carbarson	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
24.	Codelson	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
25.	DRALSERP	54	Name identified in Drugs @FDA database. This is a discontinued product with no generic equivalent available. Withdrawn FR Effective 07/01/2009
26.	Eqvalan	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
27.	Levallorphan	51	This product was marketed under the name Lorfan. Drugs @FDA database indicated this is a discontinued product with no generic equivalent.
28.	Maoson	50	Name identified in RxNorm database. RedBook database indicated this product as discontinued on 06/01/1996 with no generic eqivalent.
29.	Nalspan	56	Name identified in RxNorm database. RedBook database indicated this product as discontinued on 10/14/2006 with no generic eqivalent.

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No.	Name	POCA Score (%)	Failure preventions
30.	TEGISON	50	Name identified in Drugs @FDA database. This is a discontinued product with no generic equivalent available. Withdrawn FR Effective 09/10/2003
31.	TOVALT ODT	52	Name identified in Drugs @FDA database. This is a discontinued product with no generic equivalent available. Withdrawn pending FR Notice 04/25/2007
32.	Tylvalosin	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
33.	Valbazen	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
34.	VALPIN 50	57	Name identified in Drugs @FDA database. This is a discontinued product with no generic equivalent available. Withdrawn FR Effective Status 08/20/2010.
35.	Valtrum	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
36.	Valu-Foam	50	Name identified in RxNorm database. RedBook database indicated this product as discontinued on 12/17/1997 with no generic eqivalent.
37.	Vivalan	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

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

No.	Name	POCA Score (%)
1.	Albalon	50
2.	Calphron	52
3.	(b) (4)	54
4.	Chymar-zon	52
5.	Cibacalcin	51
6.	Cytacon	50
7.	Dalalone	54
8.	Dalgan	52
9.	Darvon	51
10.	Delalutin	54
11.	Delaxin	50
12.	Delfen	52
13.	Deltalin	51
14.	Depacon	54
15.	Dermalzone	50
16.	Desoxyn	50
17.	Dexacen-4	51
18.	Diflucan	50
19.	Digisan	52
20.	Disalcid	54
21.	Dralzine	56
22.	Duadacin	52
23.	Duphaston	56
24.	Dura ron	50
25.	Duraclon	55
26.	Duralone	51
27.	Duralutin	54
28.	Duration	51
29.	Duvadilan	52
30.	Dynacin	61
31.	Dynapen	56
32.	Dynaxin	58
33.	Dyphylline	51
34.	Dyphysin	56
35.	Fibercon	52
36.	Gavilyte-N	54
37.	Gaviscon	54
38.	Genaton	50
39.	Maxolon	50
40.	Mesulfen	54

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No.	Name	POCA Score (%)
41.	Miacalcin	51
42.	Midol teen	52
43.	Mivacron	56
44.	Mobilan	50
45.	Mygdalon	61
46.	Mylaxen	50
47.	Mysoline	50
48.	Nalfon	59
49.	Nasalfent	50
50.	Navelbine	50
51.	Novolin	52
52.	Novolin 70/30	52
53.	Novolin n	50
54.	Nuvarden	52
55.	Palpeon	52
56.	Pathilon	52
57.	Pavagen	50
58.	Pavulon	58
59.	Probalan	50
60.	Pyril tann-12	58
61.	Saralasin	50
62.	Sebulon	53
63.	Selsun	56
64.	Sylatron	50
65.	Synalar N	53
66.	Synaplin	50
67.	Tessalon	54
68.	Tiadilon	50
69.	Tobralcon	60
70.	Trilafon	51
71.	Tylefon	52
72.	Vanacon	52
73.	Vasaten	53
74.	Vaseline	50
75.	Vasocon	54
76.	Vazotan	52
77.	Velban	52
78.	Velsyn	60
79.	Veltin	54
80.	Verelan	51
81.	Viceton	52
82.	Virilon	56
83.	Vistacon	51

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No.	Name	POCA Score (%)
84.	Vivarin	50
85.	Wal-som	52
86.	Zaleplon	52
87.	Zonalon	53
88.	Zydaclin	52

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08/12/2014

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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 Memorandum

Date:	March 20, 2014
Reviewer:	Jean Olumba, MD, PharmD Division of Medication Error Prevention and Analysis
Acting Team Leader:	Lisa Khosla, PharmD, MHA Division of Medication Error Prevention and Analysis
Drug Name and Strength:	(b) (4) (nebivolol and valsartan) Tablets, 5 mg/80 mg, 5 mg/160 mg, 10 mg/160 mg, 10 mg/320 mg, 20 mg/320 mg
Application Type/Number:	NDA 206302
Applicant/sponsor:	Forest Laboratories, Inc.
OSE RCM#:	2014-17006

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