CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208612Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	January 5, 2018
Application Type and Number:	NDA 208612
Product Name and Strength:	Balcoltra (levonorgestrel/ethinyl estradiol and ferrous bisglycinate) tablet 0.1 mg/0.02 mg and 36.5 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Neuvosyn Laboratories, LLC
Panorama #:	2017-19657181
DMEPA Safety Evaluator:	Briana Rider, PharmD
DMEPA Team Leader:	Lolita White, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Balcoltra, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name. However, the submission makes reference to the external study conducted by (b) (4), which was included in the September 27, 2017 request for proprietary name submission.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4)*** on June 8, 2017. However, we found the name, (b) (4)*** unacceptable (b) (4) (b) (4) (b) (4) on September 5, 2017.[a]

On September 27, 2017, the Applicant submitted the proposed proprietary name, (b) (4)***. However, the Applicant withdrew their request for review of the proprietary name, (b) (4)***, on November 15, 2017.

Subsequently, the Applicant submitted the proposed proprietary name, (b) (4)*** for review on November 20, 2017. However, on December 5, 2017 we found the name, (b) (4)*** unacceptable (b) (4)[b]

Thus, the Applicant submitted the name, Balcoltra, for review on December 14, 2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 14, 2017 proprietary name submission.

- Intended Pronunciation: BALL-coll-TRA
- Active Ingredient: levonorgestrel/ethinyl estradiol and ferrous bisglycinate
- Indication of Use: Prevention of pregnancy
- Route of Administration: Oral
- Dosage Form: Tablet
- Strength: 0.1 mg/0.02 mg and 36.5 mg
- Dose and Frequency: One tablet by mouth once daily

[a] Fava, W. Proprietary Name Review for (b) (4)(NDA 208612). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 SEP 05. Panorama No. 2017-15537028.

[b] Fava, W. Proprietary Name Review for (b) (4)(NDA 208612). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 DEC 05. Panorama No. 2017-19116657.

- How Supplied: Cartons containing individual blister packs containing 21 tablets of levonorgestrel/ethynyl estradiol and 7 tablets of ferrous bisglycinate
- Storage: 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (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[c].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Balcoltra, is based on a slight modification to an alternate name identified in their September 27, 2017 submission, which combines "balance" and "contraceptive". 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 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 20, 2017 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.

2.2.4 FDA Name Simulation Studies

Seventy-two practitioners participated in DMEPA's prescription studies. The responses did not directly 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.

One respondent in the inpatient study interpreted the proposed proprietary name as "Valbodram", which is a close hit to the veterinary product, Valbazen. We evaluated the name pair, Balcoltra and Valbazen, further and find that Valbazen is a veterinary product. Thus, we find there is minimal risk of name confusion for this name pair (see Appendix G).

[c] USAN stem search conducted on December 20, 2017.

Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified one-hundred and forty names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%**.** These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search, and FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	107
Low similarity name pair: combined match percentage score ≤54%	33

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

Our analysis of the one-hundred and forty-one names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 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 January 3, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DBRUP on January 3, 2018, they stated no additional concerns with the proposed proprietary name, Balcoltra.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

3.1 COMMENTS TO THE APPLICANT

[d] POCA search conducted on December 20, 2017 in version 4.2.

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

If any of the proposed product characteristics as stated in your December 14, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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. [e]

[e] 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 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 55% 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 ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

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 are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information 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.,

[f] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

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

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

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

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

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

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

Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% 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.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Balcoltra Study (Conducted on December 21, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Balcoltra one tablet po once daily	"Balcoltra – use as directed. Dispense one pack"
Outpatient Prescription: Balcoltra use as directed #1 pack	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

294 People Received Study
72 People Responded

Study Name: Balcoltra

Total	24	24	24	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
BALCALTRA	0	1	1	2
BALCOLTRA	11	7	22	40
BALCONTRA	0	1	0	1
BALCOTRA	0	1	0	1
BALCULTRA	0	3	0	3
BALECLTRA	1	0	0	1
BALECULTRA	0	1	0	1
BALEOLTRA	9	0	0	9
BALEOTRA	2	0	0	2
BALKOLTA	0	1	0	1
BOLCOLTRA	0	3	0	3

BOLCOLTRO	0	1	0	1
BOLCOTRA	0	1	0	1
BOLCULTRA	0	1	0	1
BOLEOLTRA	1	0	0	1
BOLKOLTRA	0	1	0	1
URCALTRA	0	1	0	1
VALBODRAM	0	0	1	1
VOLCALTRA	0	1	0	1

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

No.	**Proposed name:** Balcoltra **Established name:** levonorgestrel and ethinyl estradiol and ferrous bisglycinate **Dosage form:** Tablet **Strength(s):** 0.1 mg/0.02 mg and 36.5 mg **Usual Dose:** One tablet by mouth once daily	POCA Score (%)	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Balcoltra	100	Subject of this review.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Bactrim	57
2.	Zaltrap	56
3.	Bosatria***	55

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Balcoltra **Established name:** levonorgestrel and ethinyl estradiol and ferrous bisglycinate **Dosage form:** Tablet **Strength(s):** 0.1 mg/0.02 mg and 36.5 mg **Usual Dose:** One tablet by mouth once daily	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Alcortin A	65	This name pair has sufficient orthographic and phonetic differences.
2.	(b) (4) ***	65	This name pair has sufficient orthographic and phonetic differences.
3.	Belsomra	64	This name pair has sufficient orthographic and phonetic differences.
4.	Dulcolax	62	This name pair has sufficient orthographic and phonetic differences.
5.	Polycitra	62	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Balcoltra **Established name:** levonorgestrel and ethinyl estradiol and ferrous bisglycinate **Dosage form:** Tablet **Strength(s):** 0.1 mg/0.02 mg and 36.5 mg **Usual Dose:** One tablet by mouth once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
6.	Caldolor	61	This name pair has sufficient orthographic and phonetic differences.
7.	Ala-Cort	60	This name pair has sufficient orthographic and phonetic differences.
8.	Balnetar	60	This name pair has sufficient orthographic and phonetic differences.
9.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences. (b) (4)
10.	Bisco-Lax	60	This name pair has sufficient orthographic and phonetic differences.
11.	Caltro	60	This name pair has sufficient orthographic and phonetic differences.
12.	Delcort	60	This name pair has sufficient orthographic and phonetic differences.
13.	Rocaltrol	60	This name pair has sufficient orthographic and phonetic differences.
14.	Alustra	59	This name pair has sufficient orthographic and phonetic differences.
15.	Bactroban	59	This name pair has sufficient orthographic and phonetic differences.
16.	Odactra	59	This name pair has sufficient orthographic and phonetic differences.
17.	Scalacort	59	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Balcoltra **Established name:** levonorgestrel and ethinyl estradiol and ferrous bisglycinate **Dosage form:** Tablet **Strength(s):** 0.1 mg/0.02 mg and 36.5 mg **Usual Dose:** One tablet by mouth once daily	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
18.	Valchlor	59	This name pair has sufficient orthographic and phonetic differences.
19.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences. (b) (4)
20.	Bicitra	58	This name pair has sufficient orthographic and phonetic differences.
21.	Blocadren	58	This name pair has sufficient orthographic and phonetic differences.
22.	Coal Tar	58	This name pair has sufficient orthographic and phonetic differences.
23.	Kaletra	58	This name pair has sufficient orthographic and phonetic differences.
24.	Spacol T/S	58	This name pair has sufficient orthographic and phonetic differences.
25.	Tums Ultra	58	This name pair has sufficient orthographic and phonetic differences.
26.	Carbatrol	57	This name pair has sufficient orthographic and phonetic differences.
27.	Soolantra	57	This name pair has sufficient orthographic and phonetic differences.
28.	Calcarb	56	This name pair has sufficient orthographic and phonetic differences.
29.	Calcitriol	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Balcoltra **Established name:** levonorgestrel and ethinyl estradiol and ferrous bisglycinate **Dosage form:** Tablet **Strength(s):** 0.1 mg/0.02 mg and 36.5 mg **Usual Dose:** One tablet by mouth once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
30.	colocort	56	This name pair has sufficient orthographic and phonetic differences.
31.	Decalcitrol	56	This name pair has sufficient orthographic and phonetic differences.
32.	Econtra	56	This name pair has sufficient orthographic and phonetic differences.
33.	Glycolax	56	This name pair has sufficient orthographic and phonetic differences.
34.	Nasalcrom	56	This name pair has sufficient orthographic and phonetic differences.
35.	Polycitra-K	56	This name pair has sufficient orthographic and phonetic differences.
36.	Baza Clear	55	This name pair has sufficient orthographic and phonetic differences.
37.	Lactaid Ultra	55	This name pair has sufficient orthographic and phonetic differences.
38.	Tobralcon	55	This name pair has sufficient orthographic and phonetic differences.
39.	Bactocill	54	This name pair has sufficient orthographic and phonetic differences.
40.	Almora	52	This name pair has sufficient orthographic and phonetic differences.
41.	Alora	52	This name pair has sufficient orthographic and phonetic differences.
42.	Carbacot	51	This name pair has sufficient orthographic and phonetic differences.
43.	Cortalo	51	This name pair has sufficient orthographic and phonetic differences.
44.	Accolate	50	This name pair has sufficient orthographic and phonetic differences.
45.	Aclaro	50	This name pair has sufficient orthographic and phonetic differences.
46.	B-Caro-T	50	This name pair has sufficient orthographic and phonetic differences.
47.	Clolar	50	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Balcoltra **Established name:** levonorgestrel and ethinyl estradiol and ferrous bisglycinate **Dosage form:** Tablet **Strength(s):** 0.1 mg/0.02 mg and 36.5 mg **Usual Dose:** One tablet by mouth once daily	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
48.	Cobalt Acetate	50	This name pair has sufficient orthographic and phonetic differences.
49.	Tol-Tab	50	This name pair has sufficient orthographic and phonetic differences.
50.	Lortab	49	This name pair has sufficient orthographic and phonetic differences.
51.	Lortab 10	49	This name pair has sufficient orthographic and phonetic differences.
52.	Acerola C	46	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

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.	Calcort	66	International product marketed in Germany, Brazil, Mexico, Switzerland, Venezuela and United Kingdom, and formerly marketed in Ireland.
2.	(b) (4) ***	66	Proposed proprietary name for ANDA 207304 found to be conditionally acceptable (OSE # 2014-25469 dated 11/19/2014). Name withdrawn by the Applicant and product approved under proprietary name, Incassia.

No.	Name	POCA Score (%)	Failure preventions
3.	(b) (4) ***	63	Proposed proprietary name for ANDA 091193 found to be conditionally acceptable (OSE # 2012-222 dated 06/13/2012). ANDA 091193 subsequently received two Complete Responses on 04/25/2013 and 10/03/2014. ANDA 091193 was approved on 05/03/2016 without a proprietary name.
4.	Biclora	62	Name identified in RxNorm database. Brand deactivated with no generic equivalent available.
5.	alcloxa	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Alcortin	60	Name identified in RxNorm database. Brand deactivated with no generic equivalent available.
7.	Altocor	60	This is the previous proprietary name for NDA 021316, and the product is approved under proprietary name Altoprev.
8.	Betaloc-Sa	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	Bitolterol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Diocalm Ultra	60	International product marketed in the UK.
11.	Sarna Ultra	60	Name identified in RxNorm database. Brand deactivated with no generic equivalent available.
12.	Voltarol Sr	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Valturna	59	Brand discontinued with no generic equivalent available. NDA 022217 withdrawn FR effective 12/05/2014.
14.	Bd Alcohol	58	Product is not a drug. It is a disinfectant prep pad.
15.	Bextra	58	Product withdrawn from the market due to safety concerns. NDA 021341 Withdrawn FR Effective 08/02/13. No generic equivalents available.
16.	Biclora-D	58	Name identified in RxNorm database. Brand deactivated with no generic equivalent available.
17.	C12-13 alcohols	58	Product is not a drug. It is a chemical name.
18.	C12-15 alcohols	58	Product is not a drug. It is a chemical name.
19.	C12-16 alcohols	58	Product is not a drug. It is a chemical name.
20.	C14-22 alcohols	58	Product is not a drug. It is a chemical name.
21.	C20-22 alcohols	58	Product is not a drug. It is a chemical name.
22.	C30-50 alcohols	58	Product is not a drug. It is a chemical name.

No.	Name	POCA Score (%)	Failure preventions
23.	Valclair	58	International Product formerly marketed in the United Kingdom.
24.	Balanta	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
25.	Baycol	57	Brand discontinued with no generic equivalent available. NDA 020740 withdrawn FR effective 08/18/2017.
26.	Bengay Ultra	57	International product marketed in the Philippines, Singapore, and formerly marketed in Hong Kong.
27.	Orajel Ultra	57	Name identified in RxNorm database. Brand deactivated with no generic equivalent available.
28.	Aloe Cort	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
29.	Balacet	56	Name identified in RxNorm database. Brand deactivated with no generic equivalent available.
30.	Balancer	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
31.	Balneol-Hc	56	ANDA 088041 withdrawn FR effective 03/31/1994.
32.	Bedranol Sr	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
33.	Bile Salts	56	Name identified in RxNorm database. Brand deactivated with no generic equivalent available.
34.	Calcilat	56	International product formerly marketed in the UK.
35.	Caltrate	56	International product formerly marketed in Australia and Israel.
36.	coldloc-La	56	Product withdrawn from the market due to safety concerns. Product contained phenylpropanolamine.
37.	colytrol	56	Name identified in RxNorm database. Brand deactivated with no generic equivalent available.
38.	Flextra	56	Name identified in RxNorm database. Brand deactivated with no generic equivalent available.
39.	Malt Extract	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
40.	Mylanta Ultra	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
41.	Aldoclor	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
42.	Aldoclor-150	55	Brand discontinued with no generic available. NDA 016016 withdrawn FR Effective 06/16/2006.
43.	Aldoclor-250	55	Brand discontinued with no generic available. NDA 016016 withdrawn FR Effective 06/16/2006.
44.	Bacter-Aid	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	Baratol	55	International product formerly marketed in Ireland, the UK, and South Africa.
46.	Blancophor R	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
47.	coldec-Tr	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
48.	Xatral Sr	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
49.	Aloe Extract	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
50.	Calcitab	54	International product marketed in Portugal.
51.	Carb-O-Lac	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
52.	Cola Extract	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
53.	Alacol	53	Name identified in RxNorm database. Brand deactivated with no generic equivalent available.
54.	Altorant	53	Name identified in RxNorm database. Brand deactivated with no generic equivalent available.
55.	Batilol	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
56.	(b) (4) ***	52	Proposed proprietary name for NDA 022352 and NDA 022351 found unacceptable by DMEPA (OSE# (b) (4)). NDA 022352 and NDA 022351 approved under proprietary name, Colcrys.
57.	Cebatrol	51	International product marketed in Canada.

No.	Name	POCA Score (%)	Failure preventions
58.	Cobalt	50	Product is not a drug. Product is a chemical element.
59.	Aloral	49	International Product formerly marketed in the United Kingdom.
60.	Lortab 0.5/33.3	49	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
61.	Brom-A-Cot	48	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
62.	Carbachol	48	International Product formerly marketed in the United Kingdom.
63.	Labrocol	48	International Product formerly marketed in the United Kingdom.
64.	Acerola	47	Name identified in RxNorm database. Brand deactivated with no generic equivalent available.
65.	Tobacco Leaf Extract	47	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
66.	Locabiotal	45	International product formerly marketed in Mexico, France, Belgium, Brazil, Greece, Hong Kong, Ireland, Malaysia, the Philippines, South Africa, Switzerland, Turkey, the UK, and Italy.
67.	Valbazen	39	Veterinary product.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[g].

No.	Name	POCA Score (%)
1.	Glucotrol	60
2.	Terra-Cortril	60
3.	Caldecort	58
4.	Darcalma	58
5.	Dilacor Xr	58
6.	Scalp-Cort	58
7.	Valicot	58

[g] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

No.	Name	POCA Score (%)
8.	Dexacort-La	57
9.	Valtoco***	57
10.	Altoprev	56
11.	Citalopram	56
12.	Cyclobral	56
13.	Paxil Cr	56
14.	Salsalte	56
15.	Xalkori	56
16.	Daypro Alta	55
17.	Maltol	55
18.	Molecular Af	55

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

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/s/

BRIANA B RIDER
01/05/2018

LOLITA G WHITE
01/08/2018

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:	December 5, 2017
Application Type and Number:	NDA 208612
Product Name and Strength:	(b) (4) (levonorgestrel and ethinyl estradiol and ferrous bisglycinate) Tablets 0.1 mg/0.02 mg and (b) (4) mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Neuvosyn Laboratories LLC.
Panorama #:	2017-19116657
DMEPA Safety Evaluator:	Walter Fava, RPh., MSEd.
DMEPA Team Leader:	Lolita White, PharmD.
DMEPA Deputy Director (acting):	Danielle Harris, PharmD.
DMEPA Director:	Todd Bridges, RPh.

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/s/

WALTER L FAVA
12/05/2017

LOLITA G WHITE
12/05/2017

DANIELLE M HARRIS
12/05/2017

TODD D BRIDGES
12/05/2017

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:	September 5, 2017
Application Type and Number:	NDA 208612
Product Name and Strength:	(b) (4) (levonorgestrel and ethinyl estradiol and ferrous bisglycinate) Tablets 0.1 mg/0.02 mg and (b) (4) mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Neuvosyn Laboratories, LLC
Panorama #:	2017-15537028
DMEPA Safety Evaluator:	Walter Fava, RPh., MSEd.
DMEPA Team Leader:	Lolita White, PharmD.
DMEPA Deputy Director:	Danielle Harris, PharmD.
DMEPA Director:	Todd Bridges, RPh.

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/s/

LOLITA G WHITE on behalf of WALTER L FAVA
09/05/2017

LOLITA G WHITE
09/05/2017

DANIELLE M HARRIS
09/05/2017

TODD D BRIDGES
09/05/2017