

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022517Orig1s000

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: April 18, 2018
Application Type and Number: NDA 022517
Product Name and Strength: Nocdurna (desmopressin acetate) sublingual tablets
(b) (4) mcg, (b) (4) mcg
Product Type: Single Ingredient Product
Rx or OTC: Rx
Applicant/Sponsor Name: Ferring Pharmaceuticals
Panorama #: 2018-20697639
DMEPA Safety Evaluator: Denise V. Baugh, PharmD, BCPS
DMEPA Team Leader: Lolita G. White, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Nocdurna, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Nocdurna on July 31, 2014. The Division of Medication Error Prevention and Analysis found the name, Nocdurna, acceptable in OSE Reviews # 2009-1488 dated November 10, 2009, # 2012-1747 dated October 24, 2012, and # 2014-26014 dated October 9, 2014. The application received a Complete Response (CR) action on April 22, 2010, January 30, 2013, and January 30, 2015. They responded to the CR December 21, 2017 and subsequently re-submitted the proposed proprietary name, Nocdurna for review on January 31, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 31, 2018.

- Intended Pronunciation: knock-DUHR-nah
- Active Ingredient: desmopressin acetate
- Indication of Use: treatment of nocturia due to nocturnal polyuria in adults who awaken two or more times each night to void
- Route of Administration: sublingual^a
- Dosage Form: sublingual tablet
- Strength: (b) (4) mcg, (b) (4) mcg^b
- Dose and Frequency: (women) (b) (4) mcg sublingually 1 hour before bedtime every evening without water; (men) (b) (4) mcg daily sublingually 1 hour before bedtime every evening without water
- How Supplied: Unit Dose Blister Box of 30 (3 x 10) and (b) (4)
- Storage: store at (b) (4); excursions permitted to 15° to 30°C (59°F to 86°F). Keep in original package to protect from moisture and light. Use immediately upon opening individual tablet blister.

^a The Applicant referred to their product as an ‘orally disintegrating sublingual tablet’ in their submission. However, in preliminary discussion with the Office of Pharmaceutical Quality (OPQ), they have determined that the dosage form for this product is a ‘sublingual tablet’.

^b (b) (4) mcg of desmopressin acetate is equivalent to 25 mcg desmopressin and (b) (4) mcg of desmopressin acetate is equivalent to 50 mcg desmopressin per preliminary discussions with the Office of Pharmaceutical Quality (OPQ). All four strengths were evaluated as part of this proprietary name review.

APPEARS THIS WAY ON ORIGINAL

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) concurred with the findings of OPDP's assessment of the proposed name. However, the Division of Bone, Reproductive, and Urologic Products (DBRUP) expressed concerns with the potential for name confusion between the proposed product name, Nocdurna and the marketed product name, Noctiva. We further evaluate the risk of name confusion in Section 2.2.3.

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

Since our last review, the Office of Pharmaceutical Quality has determined the dosage form for this product to be 'sublingual tablet'. In our previous review^d, we considered whether a modifier would be appropriate to designate the dosage form, 'sublingual tablet'. We determined that a modifier is not needed and continue to agree with our previous assessment.

2.2.3 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, February 23, 2018 e-mail, the Division of Bone, Reproductive, and Urologic Products (DBRUP) expressed their concerns relating to the proposed proprietary name at the initial phase of the review. Specifically, the division is concerned with the potential for name confusion between the proposed proprietary name, Nocdurna and the marketed proprietary name, Noctiva (desmopressin, NDA 201656).

We further assessed the potential for name confusion between the name pair Nocdurna and Noctiva and find sufficient orthographic and product characteristic differences (see Appendix E).

^c USAN stem search conducted on February 7, 2018.

^d Vee S. Proprietary Name Review for Nocdurna, NDA 022517. 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 Oct 09. RCM No.: 2014-26014.

Orthographically, the infixes of the names appear different when written. Specifically, the infix of the name Nocdurna does not contain the cross stroke letter ‘t’, which is present in the 4th position of the name Noctiva, and the letter string ‘durn’ also appears longer than the letter string ‘tiv’. These differences are difficult to overlook when the names are scripted.

The products have characteristics which differ in strength, route of administration, dose and dosage form which decrease the risk of medication error due to name confusion. Specifically, both products are available in multiple strengths. Nocdurna is proposed in (b) (4) mcg and (b) (4) mcg strengths, whereas Noctiva is approved in (7.5 mcg/mL and 15 mcg/mL) strengths. The multiple strengths make it necessary for the strength to be provided with each prescription. Also, the products have two different routes of administration (sublingual vs. nasal) and differing doses (‘1 tablet vs. ‘1 spray) which would be difficult to overlook on a prescription for these products. Lastly, the two products have different dosage forms (sublingual tablets vs nasal spray).

Although Nocdurna and Noctiva may appear immediately after one another on CPOE dropdown menus given the identical prefix letter string ‘Noc’, we find it unlikely that CPOE users would readily overlook the differences in the strength and route of administration during prescribing in an electronic system, where these are likely to be default elements displayed during the order entry process.

In summary, we do not find a risk of name confusion with this name pair.

2.2.4 FDA Name Simulation Studies

Ninety-two practitioners participated in DMEPA’s prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. We note one respondent in the inpatient study documented a response of ‘Xsovis’. We determined this response to be invalid because the response was intended for another name in the prescription simulation study. 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^e identified 65 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 1 below.

2.2.6 Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities

The proposed product, Nocdurna will be available in (b) (4) mcg and (b) (4) mcg strength(s). Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. There were no names with strength overlap and potential orthographic, spelling, and phonetic similarities with Nocdurna that were not identified in POCA.

^e POCA search conducted on April 5, 2018 in version 4.2.

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. 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 $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	64
Low similarity name pair: combined match percentage score $\leq 54\%$	0

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

Our analysis of the 65 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.9 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 April 17, 2018 of email. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DBRUP on April 17, 2018, they stated no additional concerns with the proposed proprietary name, Nocdurna.

3 CONCLUSION

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

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

If any of the proposed product characteristics as stated in your submission, received on January 31, 2018, 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 support the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

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

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

^f 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 54\%$.

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^g. 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., 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.

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

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

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

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

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

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

Step 1	<p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none">• 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	<p>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.</p>

	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • 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 ≤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. Nocdurna Name Study (Conducted on February 21, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Nocdurna 50 mcg sublingually daily</i></p>	<p>“Nocdurna – take 25 mcg sublingually daily 1 hour before bedtime, dispense # 1”</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Nocdurna 25 mcg sublingually daily 1 hour before bedtime #1</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

306 People Received Study

92 People Responded

Study Name: Nocdurna

Total	30	30	32	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
KNOCDURRNA	0	1	0	1
NACDURNA	2	0	0	2
NECDUMA	0	0	1	1
NOCDERNA	0	2	0	2
NOCDUINA	0	0	1	1
NOCDUNA	0	0	1	1
NOCDURIA	1	0	0	1
NOCDURNA	25	13	9	47
NOCTANAR	0	1	0	1
NOCTURNA	1	11	0	12
NOOCDURNA	1	0	0	1
NORDUINA	0	0	1	1
NOTDURNA	0	1	0	1
NOTURNA	0	1	0	1
NREDURMA	0	0	1	1
NVEDURNA	0	0	1	1
VARDUINA	0	0	1	1
VARDUNA	0	0	1	1
VERDUMA	0	0	1	1

VICDURA	0	0	1	1
VOCDUINA	0	0	1	1
VOC DURNA	0	0	4	4
VOCXURNA	0	0	1	1
VOEDUMA	0	0	1	1
VORDURNA	0	0	1	1
VREDIUMO	0	0	1	1
VREDREMA	0	0	1	1
VREDURMA 50MCG	0	0	1	1
VREDURNA	0	0	1	1
XSOVIS	0	0	1	1

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

No.	Proposed name: Nocdurna Established name: desmopressin Dosage form: sublingual tablet Strength(s): ^{(b) (4)} mcg, ^{(b) (4)} mcg mcg Usual Dose: (<u>women</u>) ^{(b) (4)} mcg sublingually 1 hour before bedtime every evening without water; (<u>men</u>) ^{(b) (4)} mcg daily sublingually 1 hour before bedtime every evening without water	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.	Nocdurna	100	Name is the focus of this review.

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

No.	Name	POCA Score (%)
2.	Tekturna	68
3.	Nitro-Dur	59
4.	Nicoderm CQ	57
5.	Nicoderm	64
6.	Cardura	56
7.	Luxturna	60
8.	Nucort	59
9.	Utrona-C	52
10.	Ocu-Tracin	50
11.	Nudovra***	61
12.	Numbrino***	58

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

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

No.	Proposed name: Nocdurna Established name: desmopressin Dosage form: sublingual tablet Strength(s): ^{(b) (4)} mcg, ^{(b) (4)} mcg Usual Dose: (<u>women</u>) ^{(b) (4)} mcg sublingually 1 hour before bedtime every evening without water; (<u>men</u>) ^{(b) (4)} mcg daily sublingually 1 hour before bedtime every evening without water	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.	Norcuron	70	This name pair has sufficient orthographic and phonetic differences.
14.	Enduron	60	This name pair has sufficient orthographic and phonetic differences.
15.	Danocrine	56	This name pair has sufficient orthographic and phonetic differences.
16.	Duraclon	56	This name pair has sufficient orthographic and phonetic differences.
17.	Naphcon-A	56	This name pair has sufficient orthographic and phonetic differences.
18.	Nutracort	56	This name pair has sufficient orthographic and phonetic differences.
19.	Cordran	55	This name pair has sufficient orthographic and phonetic differences.
20.	Naphcon A	56	This name pair has sufficient orthographic and phonetic differences.
21.	Novacort	56	This name pair has sufficient orthographic and phonetic differences.
22.	Endur-Acin	52	This name pair has sufficient orthographic and phonetic differences.

No.	<p>Proposed name: Nocdurna Established name: desmopressin Dosage form: sublingual tablet Strength(s): (b) (4) mcg, (b) (4) mcg Usual Dose: (women) (b) (4) mcg sublingually 1 hour before bedtime every evening without water; (men) (b) (4) mcg daily sublingually 1 hour before bedtime every evening without water</p>	<p>POCA Score (%)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
23.	Noctiva	62	<p>Orthographically, the infixes ('durn' vs. 'tiv') differ. Specifically, the infix of the name Nocdurna does not contain the cross-stroke letter 't', which is present in the 4th position of the name Noctiva, and the letter string 'durn' also appears longer than the letter string 'tiv'.</p> <p>Differing product characteristics include their strengths ((b) (4) mcg, (b) (4) mcg vs. 7.5 mcg/mL, 15 mcg/mL), their routes of administration (sublingual vs. nasal), and their dosage form (sublingual tablet vs. spray).</p>

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

No.	Name	POCA Score (%)
24.	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
25.	Tonocard	58	Brand discontinued with no generics available. NDA 018257 withdrawn FR effective June 16, 2006.
26.	Neodecadron	57	Brand discontinued with no generics available. NDA 050322 withdrawn FR effective June 16, 2006 and NDA 050324 withdrawn FR effective June 4, 2004.
27.	Valturna	56	Brand discontinued with no generics available. NDA 022217 withdrawn FR effective January 5, 2015.
28.	Cordran N	54	Brand discontinued with no generics available. NDA 050346 withdrawn FR effective September 25, 1998.
29.	Noludar	53	Brand discontinued with no generics available. NDA 009660 withdrawn FR effective April 26, 1996.
30.	Monodur	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
31.	Noctamid	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
32.	Broncodur	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
33.	Nacton	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
34.	Nucodine	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
35.	Micturin	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
36.	Dura Ron	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
37.	Neutragard	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
38.	Unburn	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
39.	Novonorm	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
40.	Curdlan	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
41.	(b) (4) ***	60	(b) (4)
42.	(b) (4) ***	62	(b) (4)

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

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

No.	Name	POCA Score (%)
43.	Decadron	64
44.	Sanctura	62
45.	Decadron-La	61
46.	Modrenal	61
47.	Blocadren	59
48.	Dicloran	59
49.	Sandrena	59
50.	Daktarin	58
51.	Incurin	58
52.	Ocu-Pred-A	58
53.	Phanodorm	57
54.	Baycadron	56
55.	Concerta	56
56.	Condrin	56
57.	D&C Brown No. 1	56
58.	D&C Green No. 8	56
59.	Decaderm	56
60.	Lusduna	56
61.	Micaderm	56
62.	Odactra	56
63.	Tudorza	56
64.	Diucardin	55
65.	Doctar	55
66.	Encora	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.	No Names

^h 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

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

/s/

DENISE V BAUGH
04/18/2018

LOLITA G WHITE
04/18/2018

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:	October 9, 2014
Application Type and Number:	NDA 22517
Product Name and Strength:	Nocurna (desmopressin) orally disintegrating sublingual tablets, 25 mcg and 50 mcg
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Ferring Pharmaceuticals, Inc.
Submission Date:	July 31, 2014
Panorama #:	2014-26014
DMEPA Primary Reviewer:	Sarah K. Vee, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The sponsor previously submitted the proposed proprietary name, Nocdurna. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Nocdurna, acceptable in OSE Reviews #2009-1488, dated November 10, 2009 and #2012-1747, dated October 24, 2012. The application received a complete response on April 22, 2010 and January 30, 2013.

Thus, the sponsor resubmitted the name, Nocdurna, for review on July 31, 2014.

1.2 PRODUCT INFORMATION

The following product information is provided in the July 31, 2014 proprietary name submission.

- Intended Pronunciation: knock-DUHR-nah
- Active Ingredient: Desmopressin
- Indication of Use: Treatment of nocturia in adults
- Route of Administration: sublingual
- Dosage Form: Orally Disintegrating Sublingual Tablets
- Strength: 25 mcg and 50 mcg
- Dose and Frequency: Women: 25 mcg daily, one hour before bedtime, administered sublingually without water. Men: 50 mcg daily, one hour before bedtime, administered sublingually without water.
- How Supplied: Unit Dose Blister Box of 30 (3 x 10) and (b) (4)
- Storage: (b) (4). Keep in original package to protect from moisture and light. Use immediately upon opening individual tablet blister.
- Container and Closure Systems: (b) (4)

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 Metabolic and Endocrinology Products (DMEP) concurred with the findings of OPDP's promotional 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 name¹.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant indicated in their submission that “noc” in the proposed name, Nocdurna, is nocturnal or nocturia and “durna” is a coined term. This proprietary name is comprised of a single 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.

The proposed name, Nocdurna, provides no indication that the product is an orally disintegrating tablet or that it is indicated to be taken sublingually. In our previous review (RCM #2012-1747, dated October 24, 2012) we considered if a modifier would be needed to indicate the dosage form and the route of administration for this product. However, adding a modifier such as “ODT” may contribute to medication errors. Many products that use “ODT” in their names are intended to be placed on the tongue whereas this product is for sublingual administration. Furthermore, we are not aware of any ODT products currently marketed that are taken sublingually. Therefore, this modifier is not appropriate for use with this product.

We also considered adding a modifier to the proposed proprietary name that would designate “sublingual (SL)”. We searched ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations² to ensure that “SL” was not on this list. We also searched ISMP's List of Products with Drug Name Suffixes³ for any other drug names that contain “SL” as part of the drug name but did not find any.

Thus, it appears that no products use a modifier to express sublingual route of administration and all products that are sublingual do not use a modifier. Therefore, we

¹USAN stem search conducted on 8/11/2014.

² <http://www.ismp.org/Tools/errorproneabbreviations.pdf> (last accessed 8/18/2014)

³ <http://www.ismp.org/tools/drugnamesuffixes.pdf> (last accessed 8/18/2014)

conclude that no modifier should be included to convey the sublingual administration of this product and that labels and labeling will be the most appropriate means of communicating these two characteristics of this product.

2.2.3 FDA Name Simulation Studies

Seventy-six 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. Most frequent misinterpretation (n = 18) was from the voice prescription where the 'd' was misinterpreted as a 't'. 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, August 20, 2014 e-mail, DMEP did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search⁴ organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	40
Low similarity name pair: combined match percentage score $\leq 49\%$	38

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

Our analysis of the 79 names contained in Table 1 determined 79 names will not pose a risk for confusion as described in Appendices C through G.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to DMEP via e-mail on September 12, 2014. At that time we also requested additional information or concerns that could inform our

⁴ POCA search conducted on 8/7/2014.

review. Per e-mail correspondence from the DMEP on September 16, 2014, they stated no additional concerns with the proposed proprietary name, Nocdurna.

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 Terrolyn Thomas, OSE project manager, at 240-402-3981.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 31, 2014 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.

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.⁵

***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?

⁵ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

- b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 49\%$.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. 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).

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

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

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

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

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

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to 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).

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 50\%$ to $\leq 69\%$).

<p>Step 1</p>	<p>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).</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any combination drug products, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> ○ 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
<p>Step 2</p>	<p>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.</p>

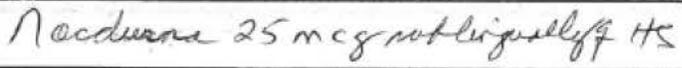
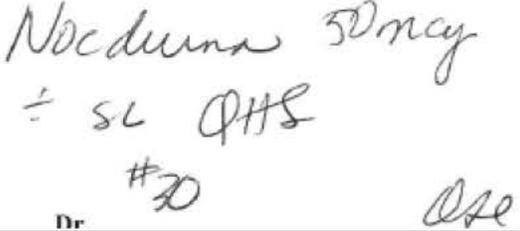
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 49\%$).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Nocdurna Study (Conducted on 8/15/2014)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Nocdurna 50 mcg 1 tablet sublingually at bedtime Disp. #30</p>
<p><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

260 People Received Study

76 People Responded

Total	28	23	25	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
NACDURNA	0	0	3	3
NOCDUANA	0	0	1	1
NOCDUNA	2	0	0	2
NOCDURA	0	0	2	2
NOCDURMA	2	0	0	2
NOCDURNA	23	5	19	47
NOCFURMN	1	0	0	1
NOCTERNA	0	3	0	3
NOCTURNA	0	15	0	15

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

No.	Name	POCA Score (%)	Failure preventions
1.	Nocdurna	100%	Subject of this review

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

No.	Name	POCA Score (%)
1.	Tekturna	66
2.	Nicoderm/CQ	60/52
3.	Materna	58
4.	Norcuron	58
5.	Mederma	56
6.	Naphcon-A	56
7.	Nudovra ***	56
8.	Sanctura	54
9.	Moderiba	53
10.	Valtunra	53
11.	Menactra	52
12.	Nicotine	52
13.	Nostrilla	52
14.	Nucort	52
15.	Nitro-Dur	51
16.	Anectine	50
17.	Micaderm	50
18.	Nicorette	50
19.	Ocu-Pred-A	50
20.	Tudorza	50

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

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

No.	Proposed name: Nocdurna Strengths: 25 mcg, 50 mcg Usual Dose: 1 tab sublingually at bedtime	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.	Noctiva ^{***}	60	The suffix of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different
2.	Nesina	54	The infix and suffix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different
3.	Natpara ^{***}	52	The infix and suffix of this name pair have sufficient orthographic differences The second and third syllables of this pair sound different

^{***} This document contains proprietary information that should not be released to the public

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

No.	Name	POCA Score (%)
1.	Maldemar	34%
2.	Meclizine	38%
3.	Meclomen	38%
4.	Mestinon	36%
5.	Micardis	40%
6.	Micatin	38%
7.	Microderm	43%
8.	Micronor	38%
9.	Moctanin	49%
10.	Moisturin	49%
11.	Naldecon	38%
12.	Nasalcrom	32%
13.	Natazia	38%
14.	Natreacor	42%
15.	Natrova	48%
16.	NeoBenz	36%
17.	Neofrin	44%
18.	Neutrexin	36%
19.	Nexterone	44%
20.	Nicotinex	44%
21.	Nicotinum	46%
22.	Niferex	30%
23.	Noctec	44%
24.	Nolamine	42%
25.	NovoFine	45%
26.	Novolin N	49%
27.	Novolin R	42%
28.	NucoTuss	44%

No.	Name	POCA Score (%)
29.	NuFrinse	44%
30.	Ventavis	<30%
31.	(b) (4)	40%
32.	Verluma	31%
33.	Victoza	41%
34.	Voltaren	38%

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.	Nucodine	60	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
2.	Micturin	58	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
3.	(b) (4) ***	58	(b) (4)
4.	(b) (4) ***	57	Found unacceptable RCM #2010-1230. NDA 200603 approved under Latuda
5.	Nacton	54	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
6.	(b) (4) ***	54	Found unacceptable RCM #2008-484. NDA 21911 approved under Banzel

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No.	Name	POCA Score (%)	Failure preventions
7.	Noctamid	54	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
8.	Noxene	54	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
9.	(b) (4) ***	53	Found unacceptable RCM# 2012-542. NDA 204063 approved under Tecfidera
10.	Nonanal	53	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
11.	Naldorin	52	Identified in previous review. Unable to find product characteristics in commonly used drug databases.
12.	Neocidin	52	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
13.	(b) (4) ***	52	Found unacceptable RCM#2010-1554 for ANDA 90418
14.	(b) (4) ***	51	Name withdrawn for NDA 204042. Approved under Invokana
15.	(b) (4) ***	51	Name withdrawn for IND (b) (4)
16.	(b) (4) **	51	Found unacceptable RCM#2012-2631 for NDA 204078. Bloxiverz found acceptable for this NDA

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No.	Name	POCA Score (%)	Failure preventions
17.	Monodur	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
18.	Noctesed	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
19.	Novonorm	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
20.	(b) (4) ***	50	Found unacceptable RCM#2008-415. NDA 22308 approved under Besivance
21.	Propaderm A	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.

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/s/

SARAH K VEE
10/09/2014

YELENA L MASLOV
10/10/2014

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

Proprietary Name Review

Date: October 24, 2012

Reviewer: Sarah K. Vee, PharmD
Division of Medication Error Prevention and Analysis

Team Leader: Yelena Maslov, PharmD
Division of Medication Error Prevention and Analysis

Deputy Director: Kellie Taylor, PharmD, MPH
Division of Medication Error Prevention and Analysis

Division Director: Carol A. Holquist, RPh
Division of Medication Error Prevention and Analysis

Drug Name and Strengths: Nocdurna (Desmopressin) Orally Disintegrating Tablets,
25 mcg and 50 mcg

Application Type/Number: NDA 22517

Applicant/Sponsor: Ferring Pharmaceuticals, Inc.

OSE RCM #: 2012-1747

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Ferring Pharmaceuticals submitted a request for proposed proprietary name review for NDA 22517 on August 5, 2009. DMEPA found the proposed proprietary name, Nocdurna, conditionally acceptable in OSE Review #2009-1488, dated November 10, 2009 and in OSE Review #2009-2200, dated March 30, 2010. NDA 22517 received a complete response (CR) on April 22, 2010. Applicant resubmitted this NDA on July 30, 2012 and the request for proprietary name review on July 31, 2012. The dose for men was decreased from 100 mcg to 50 mcg as a response to the CR letter for this submission.

1.2 PRODUCT INFORMATION

The following product information is provided in the July 31, 2012 proprietary name submission.

- Active Ingredient: Desmopressin
- Indication of Use: Treatment of nocturia in adults
- Route of Administration: Sublingual
- Dosage Form: Orally disintegrating tablets
- Strength: 25 mcg, 50 mcg
- Dose and Frequency: 1 tablet once daily 1 hour before bedtime (women: 25 mcg and men: 50 mcg)
- How Supplied: Unit dose blister box of 30 (3 x 10)
- Storage: (b) (4) keep in original packaging to protect from moisture and light. Use immediately upon opening.
- Container and Closure Systems: (b) (4)

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The October 1, 2012 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Nocurna, is derived from combining “noc” = nocturnal or nocturia and “durna” = coined term. 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.

On September 20, 2012, DMEPA sent an email to the CMC reviewer to inquire whether the dosage form for this product could be called a "sublingual tablet" as a stand alone or could it be combined with ODT and be labeled as "orally disintegrating sublingual tablet". The CMC reviewer noted that this issue was discussed during the previous review cycle and that “sublingual” should be added to the name. The CMC reviewer commented that it would be clearest to label this product as “orally disintegrating sublingual tablets” to indicate the dosage form and the route of administration.

The proposed name, Nocurna, provides no indication that the product is an orally disintegrating tablet or that it is indicated to be taken sublingually. However, adding a modifier such as “ODT” may contribute to medication errors. Many products that use “ODT” in their names are intended to be placed on the tongue whereas this product is for sublingual administration. Furthermore, we are not aware of any ODT products currently marketed that are taken sublingually. Therefore, this modifier is not appropriate for use with this product.

We also considered adding a modifier to the proposed proprietary name that would designate “sublingual (SL)”. We searched ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations¹ to ensure that “SL” was not on this list. We also searched ISMP's List of Products with Drug Name Suffixes² for any other drug names that contain “SL” as part of the drug name but did not find any.

¹ <http://www.ismp.org/Tools/errorproneabbreviations.pdf> (last accessed 10/15/12)

² <http://www.ismp.org/tools/drugnamesuffixes.pdf> (last accessed 10/15/12)

Thus, it appears that no products use a modifier to express sublingual route of administration and all products that are sublingual do not use a modifier. Therefore, we conclude that no modifier should be included to convey the sublingual administration of this product and that labels and labeling will be the most appropriate means of communicating these two characteristics of this product.

2.2.3 FDA Name Simulation Studies

Sixty-one practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Forty-nine participants identified the name as Nocdurna. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, September 4, 2012 e-mail, DMEP did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Nocdurna. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Nocdurna identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines.

Table 1: Collective List of Potentially Similar Names (DMEPA and EPD)

Look Similar		Look Similar		Look Similar	
Name	Source	Name	Source	Name	Source
Maldemar	EPD	Natazia	EPD	Nolamine	EPD
Meclizine	EPD	Natreacor	EPD	NovoFine	EPD
Meclomen	EPD	Natrova	EPD	Novolin N	EPD
Mestinon	SE	NeoBenz	EPD	Novolin R	EPD
Micaderm	EPD	Neofrin	EPD	Nucodine	EPD
Micardis	EPD	Neutrexin	SE	NucoTuss	EPD
Micatin	EPD	(b) (4) ***	EPD	NuFrinse	EPD
Micronor	EPD	Nexterone	SE	Ventavis	EPD
Moctanin	EPD	Nicotine	EPD	(b) (4)	EPD
Moisturin	EPD	Nicotinex	EPD	Verluma	EPD

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Look Similar		Look Similar		Look Similar	
Naldecon	EPD	Nicotinum	EPD	Victoza	EPD
Naldorin	EPD	Niferex	EPD	Voltaren	DMEPA
Nasalcrom	SE	Noctec	EPD		
Sound Similar		Look and Sound Similar		Look and Sound Similar	
Microderm	EPD	Mederma	EPD	Tekturna	EPD
Sanctura	EPD	Nicoderm	EPD	Valturna	EPD
		Materna	EPD		

Our analysis of the 46 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined that all 46 names will not pose a risk for confusion as described in Appendix D through E.

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the DMEP via e-mail on September 26, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMEP on October 2, 2012, they stated no additional concerns with the proposed proprietary name, Nocdurna.

3 CONCLUSIONS

DMEPA concludes the proposed proprietary name is acceptable from a promotional and safety perspective.

If you have further questions or need clarifications, please contact Margarita Tossa, OSE project manager, at 301-796-4053.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Nocdurna, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your July 31, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

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

4 REFERENCES

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

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

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

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

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

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

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

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

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

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

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

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.

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

USPTO provides information regarding patent and trademarks.

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

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

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

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

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

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

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

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

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

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

18. *Rx List (www.rxlist.com)*

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

19. Dogpile (www.dogpile.com)

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

20. Natural Standard (<http://www.naturalstandard.com>)

Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

APPENDICES

Appendix A

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

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.³

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

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

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.⁴

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

⁴ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

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

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health

professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁵ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

⁵ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

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

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

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

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

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

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

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

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

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

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

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

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has

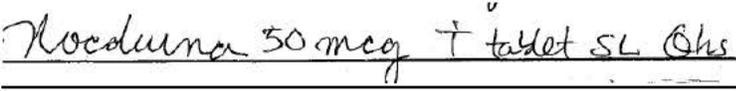
continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Nocdurna	Scripted May Appear as	Spoken May Be Interpreted as
N	M, T, V	
n	h, m, r, s, u, x	dn, gn, kn, mn, pn
o	a, c, e, i, u	any vowel
c	a, e, i, l, n, o, r, u, x	k
d	cl, ci	t
u	n, y, v, w, any vowel	any vowel
r	e, n, s, v	
a	ce, ci, cl, d, e, el, o, u, x	any vowel

Appendix C: Prescription Simulation Samples and Results

Figure 1. Nocdurna Study (Conducted on August 10, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> </p>	<p>Nocdurna 25 mcg 1 tablet sublingually every night #30</p>
<p><u>Outpatient Prescription:</u> </p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Nocdurna

184 People Received Study

60 People Responded

Study Name: Nocdurna

	17	22	22	
Total				
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
MACDONA	0	1	0	1
NOCDERMA	0	1	0	1
NOCDERNA	0	3	0	3
NOCDUINA	1	0	0	1
NOCDUNA	0	1	0	1
NOCDURNA	16	13	19	48
NOCDURNA 25 MCG 1 TAB				
SL HS	0	0	1	1
NOCTDERNA	0	1	0	1
NOCTURNA	0	2	0	2
NUCDURNA	0	0	1	1

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

No.	Proprietary Name	Active Ingredient	Similarity to Nocdurna	Failure preventions
1.	Maldemar	scopolamine	Orthographic	The pair has sufficient orthographic differences.
2.	Micardis	telmisartan	Orthographic	The pair has sufficient orthographic differences.
3.	Micatin	miconazole	Orthographic	The pair has sufficient orthographic differences.
4.	Micronor	norethindrone	Orthographic	The pair has sufficient orthographic differences.
5.	Moctanin	monoctanoin	Orthographic	NDA 19368 Withdrawn FR effective 11/12/2002
6.	Moisturin		Orthographic	Name identified in the RedBook database. Unable to find product characteristics in commonly used drug databases.
7.	Naldecon	dextromethorphan, phenylpropanolamine, guaifenesin	Orthographic	The pair has sufficient orthographic differences.
8.	Naldorin	brompheniramine, pseudoephedrine	Orthographic	The pair has sufficient orthographic differences.
9.	Natazia	estradiol valerate and estradiol valerate/dienogest kit	Orthographic	The pair has sufficient orthographic differences.
10.	Natrecor	nesiritide	Orthographic	The pair has sufficient orthographic differences.
11.	Natrova	Spinosad	Orthographic	The pair has sufficient orthographic differences.
12.	(b) (4) ***	Dimethyl Fumarate	Orthographic	Found unacceptable in OSE Review # 2012-542 for NDA 204063. (b) (4) *** under review for this NDA.
13.	Nicotine		Orthographic	The pair has sufficient orthographic differences.
14.	Nicotinum	nicotine	Orthographic	Name identified in the RedBook database. Unable to find product

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				characteristics in commonly used drug databases.
15.	Nicotinex	niacin	Orthographic	The pair has sufficient orthographic differences.
16.	Niferex	iron polysaccharide	Orthographic	The pair has sufficient orthographic differences.
17.	Nolamine		Orthographic	The pair has sufficient orthographic differences.
18.	NovoFine		Orthographic	The pair has sufficient orthographic differences.
19.	Novolin N	NPH, insulin isophane	Orthographic	The pair has sufficient orthographic differences.
20.	Novolin R	regular insulin	Orthographic	The pair has sufficient orthographic differences.
21.	Nucodine	codeine, guaifenesin, pseudoephedrine	Orthographic	The pair has sufficient orthographic differences.
22.	NucoTuss	codeine, guaifenesin, pseudoephedrine	Orthographic	The pair has sufficient orthographic differences.
23.	NaFrinse	sodium fluoride	Orthographic	The pair has sufficient orthographic differences.
24.	(b) (4) ***	crofelemer	Orthographic	Name found unacceptable OSE #2012-1477 for NDA 202292. Applicant withdrew name and submitted (b) (4) *** for review.
25.	Microderm	chlorhexidine gluconate	Phonetic	The pair has sufficient phonetic differences.
26.	Sanctura	trospium	Phonetic	The pair has sufficient phonetic differences.

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

No.	Proposed name: Nocdurna(desmopressin) Dosage Form: Orally disintegrating tablets Strengths: 25 mcg, 50 mcg Usual Dose: 1 tablet sublingually 1 hour before bedtime daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Materna (prenatal-postpartum vitamins and mineral supplement) - oral tablets - 1 tablet once daily	Orthographic Similarities - 'N' and 'M' may appear similar when scripted - 'durna' and 'terna' may appear similar when scripted Phonetic Similarities - 'durna' and 'terna' may sound similar when spoken Overlapping Product Characteristics - Dosage Form (tablet) - Dose (1 tablet) - Frequency of Administration (once daily)	Orthographic Differences - Upstroke 'ocd' at the 4 th position vs. 'at' at the 3 rd position appear different when scripted Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. single strength with no overlap)

No.	Proposed name: Nocdurna(desmopressin) Dosage Form: Orally disintegrating tablets Strengths: 25 mcg, 50 mcg Usual Dose: 1 tablet sublingually 1 hour before bedtime daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
2.	Mederma (Allium cepa) - topical gel - Apply and gently rub into scar once daily x8 weeks on new scars or 3-6 months for old scars	Orthographic Similarities - 'N' and 'M' may appear similar when scripted - 'durna' and 'derma' may appear similar when scripted Phonetic Similarities - 'durna' and 'derma' may sound similar when spoken Overlapping Product Characteristics - Frequency of Administration (once daily)	Orthographic Differences - 'oc' and 'e' appear different when scripted Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. single strength with no overlap) - Dose (Take 1 tablet vs. apply)
3.	Nicoderm CQ (nicotine) - 7 mg, 14 mg , 21 mg per 24 hour transdermal patches - More than 10/day: Weeks 1-6 use 21 mg patch/day weeks 7-8 use 14 mg then weeks 9-10 use 7 mg 10 or less/day 14 mg x6weeks then 7 mg x2 weeks	Orthographic Similarities - Both start with 'N' - 'durna' and 'derm' may appear similar when scripted Phonetic Similarities - 'durn' and 'derm' may sound similar when spoken Overlapping Product Characteristics - Frequency of Administration (once daily)	Orthographic Differences - 'ocd' and 'icod' appear different when scripted due to the position of the up stroke (4 th vs. 5 th) Phonetic Differences - 'Noc' and 'Nico' sound different when spoken Differing Product Characteristics - Strength (25 mcg, 50 mcg vs.7 mg, 14 mg, 21 mg per 24 hour) - Dose (Take 1 tablet vs. Apply 1 patch)

No.	Proposed name: Nocdurna(desmopressin) Dosage Form: Orally disintegrating tablets Strengths: 25 mcg, 50 mcg Usual Dose: 1 tablet sublingually 1 hour before bedtime daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
4.	Tekturna (aliskiren) - 150 mg, 300 mg oral tablets - 1 tablet once daily Approved 3/5/2007	Orthographic Similarities - 'durna' and 'turna' may appear similar when scripted Phonetic Similarities - 'ocdurna' and 'ekturna' may sound similar when spoken. Overlapping Product Characteristics - Dosage Form (tablets) - Dose (1 tablet) - Frequency of Administration (once daily)	Orthographic Differences - 'Noc' and 'Tek' appear different when scripted. Phonetic Differences - 'N' and 'T' sound different when spoken. Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. 150 mg, 300 mg)

No.	Proposed name: Nocdurna (desmopressin) Dosage Form: Orally disintegrating tablets Strengths: 25 mcg, 50 mcg Usual Dose: 1 tablet sublingually 1 hour before bedtime daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
5.	Valturna (aliskiren and valsartan) - 150 mg/160 mg, 300 mg/320 mg oral tablets - 1 tablet once daily Approved 9/16/2009	Orthographic Similarities - ‘durna’ and ‘turna’ may appear similar when scripted Phonetic Similarities - ‘durna’ and ‘turna’ may sound similar when spoken Overlapping Product Characteristics - Dosage Form (tablets) - Dose (1 tablet) - Frequency of Administration (once daily)	Orthographic Differences - ‘Noc’ and ‘Val’ appear different when scripted. Phonetic Differences - ‘Noc’ and ‘Val’ sound different when spoken. Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. 150 mg/160 mg, 300 mg/320 mg)
6.	Meclizine - 25 mg oral tablets - 12.5 mg, 25 mg chewable tablets - 25 mg to 100 mg in divided doses	Orthographic Similarities - ‘Nocd’ and ‘Mecl’ may appear similar when scripted. Overlapping Product Characteristics - Dosage Form (tablets) - Strength (25 mcg vs. 25 mg)	Orthographic Differences - ‘urna’ and ‘izine’ appear different when scripted

No.	Proposed name: Nocdurna (desmopressin) Dosage Form: Orally disintegrating tablets Strengths: 25 mcg, 50 mcg Usual Dose: 1 tablet sublingually 1 hour before bedtime daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
7.	Meclomen (meclofenamate) - 50 mg, 100 mg oral capsules - 1 capsule 3 to 4 times daily as needed	Orthographic Similarities - ‘Nocd’ and ‘Mecl’ may appear similar when scripted Overlapping Product Characteristics - Dosage Form (tablets/capsules) - Strength (50 mcg vs. 50 mg)	Orthographic Differences - ‘urna’ and ‘omen’ appear different when scripted
8.	Mestinon (Pyridostigmine) - 60 mg oral tablets - 60 mg per 5 mL oral syrup - 60 mg to 1,500 mg by mouth in divided doses; 1 mg/kg by mouth every 4 to 6 hours	Orthographic Similarities - ‘Nocd’ and ‘Mest’ may appear similar when scripted Overlapping Product Characteristics - Dosage Form (tablets)	Orthographic Differences - ‘urna’ and ‘inon’ appear different when scripted Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. 60 mg, 60 mg/5 mL)
9.	Micaderm (miconazole) - 2% topical cream - Apply as directed	Orthographic Similarities - ‘N’ vs ‘M’ and ‘durna’ and ‘derm’ may appear similar when scripted	Orthographic Differences - ‘ocd’ and ‘icad’ appear different when scripted due to the position of the up stroke (4 th vs. 5 th) Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. 2%) - Dose (Take 1 tablet vs. Apply as directed)

No.	Proposed name: Nocdurna(desmopressin) Dosage Form: Orally disintegrating tablets Strengths: 25 mcg, 50 mcg Usual Dose: 1 tablet sublingually 1 hour before bedtime daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
10.	Nasal crom (cromolyn sodium) - 5.2 mg per spray nasal - Spray once into each nostril. Repeat 3-4 times a day (every 4 to 6 hours) as needed	Orthographic Similarities - 'Nocdurna' and 'Nasal crom' may appear similar when scripted	Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. 5.2 mg)
11.	NeoBenz (Benzoyl Peroxide) - Micro: 3.5%, 5.5%, 8.5% cream; Micro: 7% wash; Micro SD: 3.5%, 5.5%, 8.5% cream - Apply to affected area once to four times daily	Orthographic Similarities - 'Nocd' and 'Neob' may appear similar when scripted	Orthographic Differences - 'urna' and 'enz' appear different when scripted Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. Micro: 3.5%, 5.5%, 8.5% cream; Micro: 7% wash; Micro SD: 3.5%, 5.5%, 8.5% cream)
12.	Neofrin (Phenylephrine) - 2.5%, 10% ophthalmic solution - Instill 1 or 2 drops in the eye before the procedure, may be repeated in 10 to 60 minutes if needed; Instill 1 drop to the upper surface of the cornea, may be continued the following day if necessary; Instill 1 drop of the 10% solution 3 or more times per day with a 1% to 4% solution	Orthographic Similarities - 'Nocd' and 'Neof' may appear similar when scripted	Orthographic Differences - 'urna' and 'rin' appear different when scripted Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. 2.5%, 10%)

No.	Proposed name: Nocdurna(desmopressin) Dosage Form: Orally disintegrating tablets Strengths: 25 mcg, 50 mcg Usual Dose: 1 tablet sublingually 1 hour before bedtime daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
13.	Neutrexin (Trimetrexate) - 25 mg, 200 mg injection - 1 mg/kg/day to 1.5 mg/kg/day intravenously; 45 mg/m ² intravenously once daily	Orthographic Similarities - ‘Nocd’ and ‘Neut’ may appear similar when scripted Overlapping Product Characteristics - Strength (25 mcg vs. 25 mg) - Frequency of Administration (once daily)	Orthographic Differences - ‘urna’ and ‘rexin’ appear different when scripted Differing Product Characteristics - Dose (1 tablet vs. weight or BSA based dose) Neutrexin is a discontinued product and there are no generic or therapeutic equivalents available. The product was withdrawn by the Applicant for marketing reasons with the Federal Register Notice dated February 11, 2009.
14.	Nexterone (Amiodarone) - 150 mg per 100 mL, 360 mg per 200 mL injection - Initial Load: 150 mg per 100 mL infused over 10 minutes followed by 1 mg/min for 6 hours then 0.5 mg/min thereafter	Orthographic Similarities - Both begin with ‘N’ ‘dur’ and ‘ter’ may appear similar when scripted	Orthographic Differences - ‘oc’ vs. ‘ex’ and ‘na’ vs. ‘one’ appear different when scripted Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. 150 mg/100 mL, 360 mg/200 mL) - Dose (1 tablet vs. 150 mg/100 mL, 1 mg/min, 0.5 mg/min)

No.	Proposed name: Nocdurna(desmopressin) Dosage Form: Orally disintegrating tablets Strengths: 25 mcg, 50 mcg Usual Dose: 1 tablet sublingually 1 hour before bedtime daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
15.	Noctec (chloral hydrate) - 500 mg/5 mL oral syrup - 500 mg to 1 gram before bedtime or surgery or 250 mg TID - - - Children: 50 mg/kg max of 1 gram single dose	Orthographic Similarities - 'Nocd' and 'Noct' may appear similar when scripted Overlapping Product Characteristics - Strength (50 mcg vs. 500 mg/5 mL)	Orthographic Differences - 'urna' and 'ec' appear longer and different when scripted (8 vs. 6 letters)
16.	Ventavis (Iloprost) - 10 mcg per mL, 20 mcg per mL solution for inhalation - 2.5 mcg to 5 mcg inhaled six to nine times daily	Orthographic Similarities - 'Nocd' and 'Vent' may appear similar when scripted	Orthographic Differences - 'urna' and 'avis' appear different when scripted Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. 10 mcg/mL, 20 mcg/mL)
17.	Verluma (nofetumomab) - Kit for preparation of Technetium Tc99m Nofetumomab Merpetan - 5 mg to 10 mg Nofetumomab labeled with 1,110 MBq Tc 99m in 15 mL to 20 mL NaCl solution over 3-5 min IV injection	Orthographic Similarities - 'Nocdurna' and 'Verluma' may appear similar when scripted	Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. kit) - Setting of Use (Verluma used in radiologic suite)

No.	Proposed name: Nocdurna(desmopressin) Dosage Form: Orally disintegrating tablets Strengths: 25 mcg, 50 mcg Usual Dose: 1 tablet sublingually 1 hour before bedtime daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
18.	Vectura (ethinyl estradiol, drospirenone) - 0.02 mg/3mg oral tablets - 1 tablet once daily	Orthographic Similarities - ‘Nocdurna’ and ‘Vectura’ may appear similar when scripted Overlapping Product Characteristics - Dosage Form (tablets) - Dose (1 tablet) - Frequency of Administration (once daily)	Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. 0.02 mg/3 mg single strength with no overlap)
19.	Victoza (liraglutide) - 6 mg/mL injection - Inject 0.6 mg, 1.2 mg, 1.8 mg subcutaneously once daily	Orthographic Similarities - ‘Nocd’ and ‘Vict’ may appear similar when scripted Overlapping Product Characteristics - Frequency of Administration (once daily)	Orthographic Differences - ‘urna’ and ‘oza’ appear different when scripted Differing Product Characteristics - Strength (25 mcg, 50 mcg vs. 6 mg/mL single strength with no overlap) - Dose (25 mcg, 50 mcg vs. 0.6 mg, 1.2 mg, 1.8 mg)

No.	Proposed name: Nocdurna (desmopressin) Dosage Form: Orally disintegrating tablets Strengths: 25 mcg, 50 mcg Usual Dose: 1 tablet sublingually 1 hour before bedtime daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
20.	Voltaren (Diclofenac) Delayed-release Oral Tablet: 25 mg, 50 mg, 75 mg Extended-release Oral Tablet: 100 mg Ophthalmic solution: 0.1% Topical Gel: 1% Tablet: 100 mg to 150 mg in divided doses. XR Tablets: 100 mg once daily to twice daily Ophthalmic solution: 1 to 2 drops in affected eye four times daily Topical Gel: Osteoarthritis Apply 2 to 4 grams to affected area four times daily	Orthographic Similarities - 'No' and 'Vo' may appear similar when scripted - 'durna' and 'taren' may appear similar when scripted Overlapping Product Characteristics - Strength (25 mcg, 50 mcg vs. 25 mg, 50 mg tablets)	Orthographic Differences - 2 upstrokes vs. 3 upstrokes Differing Product Characteristics - Dosage Form for Voltaren must be specified. (ODT vs. tablets, ophthalmic solution, topical gel)

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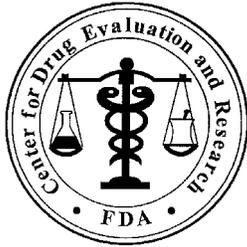
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KELLIE A TAYLOR on behalf of CAROL A HOLQUIST
10/25/2012



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date: March 30, 2010

To: Mary Parks, MD, Director
Division of Metabolism and Endocrinology Products

Through: Carlos Mena-Grillasca, RPh, Team Leader
Denise P. Toyer, PharmD, Deputy Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Judy Park, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Nocdurna (Desmopressin) Orally Disintegrating Tablets
25 mcg

Application Type/Number: NDA 022517

Applicant: Ferring Pharmaceuticals

OSE RCM #: 2009-2200

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1 INTRODUCTION

This review is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed proprietary name, Nocdurna, acceptable in OSE Review #2009-1488 dated November 10, 2009. On August 27, 2009, DDMAC reviewed the proposed proprietary name and had no concerns from a promotional perspective. Furthermore, the review Division did not have any concerns with the proposed name, Nocdurna, during our initial review.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the previous (OSE Review #2009-1488) proprietary name review. We used the same search criteria previously used and re-analyzed the names from OSE Review #2009-1488 because the male dose has been reduced from 100 mcg to 50 mcg daily. Therefore, the Applicant will only market a 25 mcg tablet in lieu of two strengths (i.e. 25 mcg and 50 mcg). DMEPA considered this new scenario in our re-evaluation of the names from the initial proprietary name review. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates.

DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis¹ (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, Nocdurna, as of March 5, 2010.

The searches of the databases referenced in Section 4 yielded no additional new names which were thought to have look-alike or sound-alike similarity to the name, Nocdurna. A re-analysis of the names identified in OSE Review #2009-1488, due to the change in strength and dose for men, did not introduce any new vulnerabilities with these names.

3 CONCLUSIONS AND RECOMMENDATIONS

The re-review of the proprietary name, Nocdurna, did not identify any additional names thought to look or sound similar to the proposed name since our last review. Additionally, we considered the new product characteristics (i.e. single strength product [25 mcg] and a 50 mcg dose for men) in our evaluation. This change in product characteristics did not introduce any new vulnerabilities. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Nocdurna, for this product at this time.

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

4 REFERENCES

1. OSE review # 2009-1488 Proprietary Name Review of Nocdurna; Toombs, L. Shenee'; November 10, 2009

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

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present.

Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.

3. *USAN Stems* (<http://www.ama-assn.org/ama/pub/category/4782.html>)

USAN Stems List contains all the recognized USAN stems.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22517	ORIG-1	FERRING PHARMACEUTICA LS INC	NOCDURNA

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

/s/

JUDY J PARK
03/30/2010

CARLOS M MENA-GRILLASCA
03/30/2010

DENISE P TOYER
03/31/2010



**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: November 10, 2009

To: Mary Parks, MD, Director
Division of Metabolism and Endocrinology Products

Through: Carlos M Mena-Grillasca, RPh, Team Leader
Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: L. Shenee' Toombs, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Nocurna (Desmopressin) Orally Disintegrating Tablets
25 mcg, 100 mcg

Application Type/Number: NDA 022517

Applicant/Applicant: Ferring Pharmaceuticals

OSE RCM #: 2009-1488

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

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EXECUTIVE SUMMARY

Nocdurna is the proposed proprietary name for Desmopressin orally disintegrating tablets. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. Additionally, our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name Nocdurna acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from Ferring Pharmaceuticals on August 5, 2009, for an assessment of the proposed proprietary name, Nocdurna, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. Ferring Pharmaceuticals also submitted container labels and carton labeling for review and comment, which will be reviewed under separate cover (OSE Review #2009-1554).

1.2 PRODUCT INFORMATION

Nocdurna (desmopressin) is an antidiuretic hormone being investigated for treatment of nocturia in adults. The usual maintenance dose is 25 mcg for women, and 100 mcg for men once daily at bedtime. Nocdurna will be supplied as 25 mcg and 100 mcg orally disintegrating tablets in boxes of 30 (3 x 10) unit dose blisters.

1.3 REGULATORY HISTORY

Nocdurna (desmopressin) is currently under review by the Division of Metabolism and Endocrinology Products under NDA 22517 with a PDUFA goal date of April 22, 2010.

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Nocdurna.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'N' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.^{1,2}

¹ Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

² Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

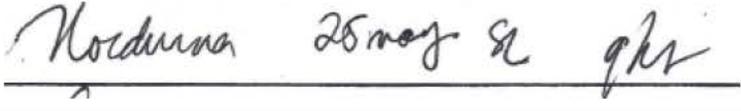
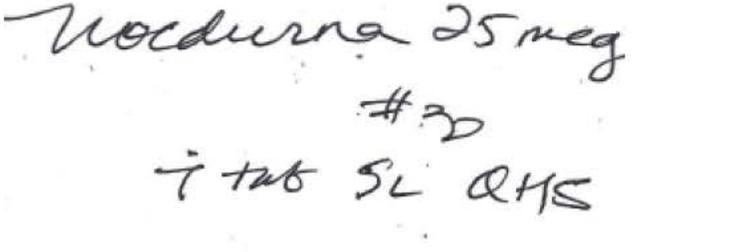
To identify drug names that may look similar to Nocdurna, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (8 letters), upstrokes (two, capital letter 'N', lowercase letter 'd'), down strokes (none), cross strokes (none), and dotted letters (none). Additionally, several letters in Nocdurna may be vulnerable to ambiguity when scripted, including the capital letter 'N' may appear as capital letters 'M', or 'V'; lower case 'o' may look like lower case 'e', 'a', or 'c'; lower case 'c' may look like lower case 'a', 'e', or 'o'; lower case letter 'd' may appear as lower case 'cl'; lower case 'u' may appear as lower case 'n', 'x', 'r' or 's'; lower case 'r' may appear as lower case 't', 'v', 'n', 'u', 'x', or 's'; lower case 'n' may appear as lower case 'm', 'v', 'r', 'h', 's', 'x', or 'u'; lower case 'a' may look like lower case 'e', 'o', or 'c'. As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Nocdurna.

When searching to identify potential names that may sound similar to Nocdurna, the DMEPA staff search for names with similar number of syllables (3), stresses (NOC-dur-na; noc-DUR-na; noc-dur-NA), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary such as 'Noc-' may sound like 'knoc', or 'not'; '-dur-' may sound like 'der', 'tur', 'ter', 'tor' or 'dir', and '-na' may sound like 'nu', 'ma', or 'mu'. The Applicant's intended pronunciation (knock-DUHR-nah) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient medication order and verbal prescription was communicated during the FDA prescription studies.

Figure 1. Nocdurna Study (conducted on September 3, 2009)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Inpatient Medication Order:</u></p> 	<p>Nocdurna 25 mcg sublingually qhs</p>
<p><u>Outpatient Medication Order:</u></p> 	

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of sixteen names as having some similarity to the name Nocdurna.

Fourteen names were thought to look like Nocdurna. These include: Nicoderm CQ, Zactima, Nicoderm, Enduron, Viadur, Moctanin, Northera^{***}, Valturna^{***}, Victoza^{***}, (b)(4)^{***}, Voltaren, Nexterone, Miraluma and Novantrone.

Two names were thought to look and sound similar to Nocdurna. These include Tekturna and Mederma.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of September 11, 2009.

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Nocdurna.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of twenty-two practitioners responded in the prescription analysis studies. Eleven of the participants interpreted the name correctly as “Nocdurna,” with correct interpretation occurring in both the inpatient and outpatient written studies. The remainder of the written responses misinterpreted the drug name. In the verbal studies, all responses were misspelled phonetic variations of the proposed name, Nocdurna. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

3.4 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator identified two additional names which were thought to look or sound similar to Nocdurna and represent a potential source of drug name confusion. One of the two names, Meclomen, looks similar to Nocdurna. One name, Noctura, was identified as having sound-alike and look-alike similarities to Nocdurna.

Upon further observation of the names identified in the database searches, the name Nicoderm, was found to be an abbreviated version of the name Nicoderm CQ. Therefore, Nicoderm was eliminated from further analysis. Thus, we evaluated a total of 17 names for their similarity to the proposed name.

3.5 COMMENTS FROM THE DIVISION OF METABOLISM AND ENDOCRINOLOGY PRODUCTS (DMEP)

In response to the OSE, August 27, 2009 e-mail, DMEP did not forward any comments and/or concerns on the proposed name at the initial phase of the name review.

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

On September 24, 2009, DMEPA notified the Division of Metabolism and Endocrinology Products via e-mail that we had no objections to the proposed proprietary name, Nocdurna. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products on October 20, 2009, they indicated that they concur with our assessment of the proposed proprietary name, Nocdurna.

4 DISCUSSION

Neither DDMAC nor the Division of Metabolism and Endocrinology Products had concerns with the proposed name. DMEPA did not identify any issues that would render the name unacceptable other than names as potential sources of confusion because of their similar sound and appearance to Nocdurna. DMEPA identified and evaluated seventeen names for their potential similarity to the proposed name, Nocdurna. Four of the seventeen names lacked orthographic and/or phonetic similarity and were eliminated from further evaluation (see Appendix C).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining thirteen names and lead to medication errors. This analysis determined that the name similarity between Nocdurna was unlikely to result in medication errors with any of the thirteen products for the reasons presented in Appendices D through J.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Nocdurna, is not vulnerable to name confusion that could lead to medication errors nor was the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) have no objection to the proprietary name, Nocdurna, for this product at this time.

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If the approval of this application is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation.

We are willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Mildred Wright, project manager, at 301-796-1027.

5.1 COMMENTS TO THE APPLICANT

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

Nocdurna will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

6 REFERENCES

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

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

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

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

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

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

4. ***AMF Decision Support System [DSS]***

DSS is a government database used to track individual submissions and assignments in review divisions.

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

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

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

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.

7. ***Electronic online version of the FDA Orange Book*** (<http://www.fda.gov/cder/ob/default.htm>)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

USPTO provides information regarding patent and trademarks.

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

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

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

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

11. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

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

12. Stat!Ref (www.statref.com)

Stat!Ref contains full-text information from approximately 30 texts; it includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology, and Dictionary of Medical Acronyms Abbreviations.

13. USAN Stems (<http://www.ama-assn.org/ama/pub/category/4782.html>)

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

15. Lexi-Comp (www.lexi.com)

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

16. Medical Abbreviations Book

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

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. 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

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases

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

the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.⁴ DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.⁵ DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., “T” may look like “F,” lower case ‘a’ looks like a lower case ‘u,’ etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the Applicant’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

⁴ Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

⁵ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

Type of similarity	Considerations when searching the databases		
	<i>Potential causes of drug name similarity</i>	<i>Attributes examined to identify similar drug names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

1. Database and Information Sources

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

3. FDA Prescription Analysis Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of the 123 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 send their interpretations of the orders via e-mail to DMEPA.

4. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and 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 DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or 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 concur/not concur with DMEPA's final decision.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁶ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion.

⁶ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?”

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

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

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

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

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

- a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant select an alternative proprietary name

and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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

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

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Applicants’ have changed a product’s proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners’ vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. . (See Section 4 for limitations of the process).

Appendix B: FDA Prescription Study Responses.

Inpatient Medication Order	Outpatient Medication Order	Voice Prescription
Nocdurna	Nocdurna	Nocturna
Nocdurva	Nordurna	Nocturna
Nocdurva	Nocdurna	Nocturna
Nocduriva	Nocdurna	Nocturna
Nocdurna	Nocdurna	Nocturna
Nocduran	Nocdurnia	
Nocdurna		
Nocdurva		
Nocdurna		
Nocdurna		
Nocdurna		

Appendix C: Proprietary names that lack convincing orthographic and/or phonetic similarities

Proprietary Name	Similarity to Nocdurna
Enduron	Look
Victoza ^{***}	Look
Tekturna	Sound

Appendix D: Discontinued products with no available generics

Proprietary Name	Active Ingredient	Similarity to Nocdurna
Moctanin	Monoctanoin	Look

Appendix E: Over-the-counter homeopathic preparation no longer marketed

Proprietary Name	Similarity to Nocdurna	Reason for Discard
Noctura	Look and Sound	Currently marketed under the Sleep-Aid trademark

Appendix F: Proposed proprietary names that were approved under a different proprietary name

Proprietary Name	Similarity to Nocdurna	Reason for Discard
(b) (4) ^{***}	Look	Approved under the name Vimpat

Appendix G: Proposed proprietary names withdrawn prior to approval

Proprietary Name	Similarity to Nocdurna	Reason for Discard
Zactima ^{***}	Look	Entire NDA including Proprietary name withdrawn by Manufacturer- October 27, 2009

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

Appendix H: Products with no overlap in strength and usual dose

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Nocdurna (Desmopressin) Orally Disintegrating Tablet		25 mcg, 100 mcg	Women: 25 mcg once daily at bedtime Men: 100 mcg once daily at bedtime
Viadur (Leuprolide)	Look	Implant: 65 mg (free base)	Insert one implant subcutaneously (Remove after 12 months)
Miraluma (Technetium TC-99M Sestabibi Kit)	Look	Injection: 5 ml vial	Diagnostic Agent used in Myocardial/Breast Imaging: Single Dose (intravenous): 740 to 1110 MBq (20-30 mCi)

Appendix I: Products with multiple differentiating product characteristics

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Differentiating product characteristics
Nocdurna (Desmopressin) Orally Disintegrating Tablet		25 mcg, 100 mcg	Women: 25 mcg once daily at bedtime Men: 100 mcg once daily at bedtime	
Nicoderm CQ (Nicotine)	Look	Transdermal Patch: 21 mg/24 hr; 14 mg/24 hr; 7 mg/24 hr	Reduces nicotine withdrawal symptoms Apply one new patch every 24 hours on skin that is dry, clean and hairless.	Route of Administration: Sublingual vs. Topical Dosage Form: Tablet vs Patch Dose: 25 mcg or 100 mcg vs. 7 mg to 21 mg
Nexterone (Amiodarone)	Look	Vials: 150 mg/3 mL; 450 mg/9mL; 900 mg/18 mL Syringe: 150 mg/3 mL	Starting dose: 1000 mg over first 24 hours Initial load: 150 mg over 10 minutes Followed by: 1 mg/min for 6 hours Followed by 0.5 mg/min thereafter	Route of Administration: Sublingual vs. Intravenous Dosage Form: Tablet vs Injection Dose: 25 mcg or 100 mcg vs. 150 mg; 1 mg/min; 0.5 mg/min
Novantrone (Mitoxantrone)	Look	Injection: 20 mg/10 mL	Multiple Sclerosis: 12 mg/m ² intravenous infusion every 3 months. Hormone-Refractory Prostate Cancer: 12 to 14 mg/m ² intravenous infusion every 21 days. Combination Initial Therapy for Acute-non lymphocytic leukemia : 12 mg/m ² intravenous infusion daily for 3 days	Route of Administration: Sublingual vs. Intravenous Dosage Form: Tablet vs Injection Frequency of Administration: once daily vs. every 3 months, every 21 days, every 3 days.
Mederma (Allium cepa)	Look and Sound	Mederma Gel Mederma Cream plus SPF 30 Mederma for Kids	Apply a thin layer to affected area three to four times a day	Route of Administration: Sublingual vs. Topical Dosage Form: Tablet vs Cream/Gel Frequency of Administration: once daily vs. three to four times daily

Appendix J: Proprietary names with orthographic and phonetic differences and differing product characteristics which will minimize confusion that could lead to medication errors.

Proposed name: Nocdurna (Desmopressin) Orally Disintegrating Tablet	Strength: 25 mcg, 100 mcg	Usual dose: Women: 25 mcg once daily at bedtime Men: 100 mcg once daily at bedtime
Failure Mode: Name confusion	Causes (could be multiple)	Rationale:
<p>Valturna *** (Aliskiren/Valsartan)</p> <p>Capsule: 150 mg/160 mg, 300 mg/320 mg</p> <p><i>Indication:</i> Hypertension</p> <p><i>Dose:</i> Start dose: 150 mg/160 mg once daily; Titrate to a maximum dose of 300 mg/320 mg</p>	<p>Orthographic similarity:</p> <p>Both names are similar in shape (upstrokes) and length (8 letters)</p> <p>Both names end with the letters “urna”</p> <p>Similarity in frequency of administration—(once daily at bedtime vs once daily)</p> <p>Valturna orders/prescriptions written for one component of the tablet strength and dose designation “mg” misinterpreted as “mcg”.</p>	<p>Medication errors unlikely to occur due to the orthographic differences and differing product characteristics.</p> <p><i>Rationale:</i></p> <p>Although Nocdurna and Valturna have the same word shape. The two products begin with different letters, ‘N’ vs ‘V’ and the beginning letter string for both names (‘Noc’ vs. ‘Val’) has a different visual appearance. Valturna has two upstrokes, whereas Nocdurna has only one (‘l’ vs. ‘d’) and Valturna contains a letter with a cross stroke (‘t’), and Nocdurna does not.</p> <p>Valturna and Nocdurna are available in two strengths thus a strength will be required when ordering/prescribing. Additionally, since Valturna is a combination product prescribers may include both components strengths (e.g. Valturna 150 mg/160 mg) when ordering this product. However, if Valturna is ordered using only one of the respective strengths (e.g., Valturna 150 mg or 300 mg) the dose of Valturna is achievable using available strengths of Nocdurna.</p> <ul style="list-style-type: none"> • The dose designation “mg” would have to be misinterpreted as “mcg”. • The health care professional would have to overlook that a Nocdurna dose of 150 mg or 300 mg would result in an overdose for both males and females. • The prescriber would have to omit the additional instructions for use for Nocdurna which may include SL, sublingually or place under the tongue. Alternatively, the dispenser would have to overlook these instructions if they are present on a prescription. • The dose would require a patient to take three sublingual tablets to achieve the dose (i.e. one 100 mcg tablet + two 25 mcg tablets or three 100 mcg tablets). The need for 3 separate tablets for one dose to be given sublingually may alert a pharmacist to question the order.
<p>Northera *** (Droxidopa)</p> <p>Capsule: 100 mg, 200 mg, 300 mg</p> <p><i>Indication:</i> Hypotension</p> <p><i>Dose:</i> 300 mg to (b) (4) mg in three divided doses</p>	<p>Orthographic similarity:</p> <p>Both names begin with the letters “No”</p> <p>Both names end with the letter ‘a’</p> <p>Both names are similar in shape (upstrokes) and length (8 letters)</p> <p>Numerical overlap in strength and unit similarity (100 mcg vs 100 mg):</p>	<p>Medication errors unlikely to occur due to the orthographic and differing product characteristics between Nocdurna and Northera</p> <p><i>Rationale:</i> Although Nocdurna and Northera have the same word shape. Northera has two upstrokes, whereas Nocdurna has one (‘th’ vs. ‘d’). Northera contains a letter with a cross stroke (‘t’), and Nocdurna does not.</p> <p>N o c d u r n a N o r t h e r a</p> <p>Also, the third letter in Nocdurna (‘c’), has a rounded shape which is different from the third letter in Northera (‘r’), and gives the name Nocdurna a different appearance.</p> <p>In addition to the orthographic differences, medication errors are unlikely to occur due to differing product characteristics:</p> <p>Frequency of administrations (once daily at bedtime vs. tid)</p> <p>Although both are oral (sublingual vs. oral), prescribers may provide additional instructions for use, such as SL, sublingually or place under the tongue for Nocdurna which will also help differentiate the two products.</p>

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

Appendix J (cont'd): Proprietary names with orthographic and phonetic differences and differing product characteristics which will minimize confusion that could lead to medication errors.

Proposed name: Nocdurna (Desmopressin) Orally Disintegrating Tablet	Strength: 25 mcg, 100 mcg	Usual dose: Women: 25 mcg once daily at bedtime Men: 100 mcg once daily at bedtime
Failure Mode: Name confusion	Causes (could be multiple)	Rationale:
<p>Voltaren (Diclofenac) Delayed-release Tablet; 25 mg, 50 mg, 75 mg Ophthalmic solution: 0.1% Topical Gel: 1%</p> <p><i>Indication:</i> Tablet: Osteoarthritis, Rheumatoid Arthritis, Ankylosing Spondylitis 100 mg-200 mg in two – four divided doses</p> <p>Ophthalmic solution: Post-operative inflammation in Cataract extraction; Relief of pain and photophobia in corneal refractive surgery One to two drops in affected eye four times daily</p> <p>Topical Gel: Osteoarthritis Apply two to four grams to affected area four times daily</p>	<p>Orthographic similarity: Both names are similar in shape (upstrokes) and length (8 letters)</p> <p>Numerical overlap in strength and unit similarity (25 mcg vs 25 mg):</p>	<p>Medication errors unlikely to occur due to the orthographic and differing product characteristics between Nocdurna and Voltaren</p> <p><i>Rationale:</i> Although Nocdurna and Voltaren have the same word shape. The two products begin with different letters, ‘N’ vs ‘V’. Voltaren has two upstrokes, whereas Nocdurna only has one (‘l’ vs. ‘d’). In addition, Voltaren contains a letter with a cross stroke (‘t’), and Nocdurna does not.</p> <p style="text-align: center;">N o c d u r n a V o l t a r e n</p> <p>In addition to the orthographic differences, medication errors are unlikely to occur due to differing product characteristics:</p> <p><i>For ophthalmic solution and topical gel products:</i> The different strengths and dosage form will help differentiate Nocdurna from these products.</p> <p><i>For tablets:</i> Frequency of administration (once daily at bedtime vs. two to four times daily)</p> <p>Although both are oral (sublingual vs. oral), prescribers may provide additional instructions for use, such as SL, sublingually or place under the tongue for Nocdurna which will also help differentiate the two products.</p>
<p>Meclomen (Meclofenamate) Capsule: 50 mg, 100 mg</p> <p><i>Indication:</i> Excessive Menstrual blood loss and primary dysmenorrhea; Mild to moderate pain; Osteoarthritis; Rheumatoid Arthritis</p> <p><i>Dose:</i> 200 mg to 400 mg per day in three to six divided doses</p>	<p>Orthographic similarity: Both names are similar in shape (upstrokes) and length (8 letters)</p> <p>The letter string “cl” in Meclomen may be misinterpreted as “d” when scripted.</p> <p>Numerical overlap in strength and unit similarity (100 mcg vs 100 mg):</p>	<p>Medication errors unlikely to occur due to orthographic and differing product characteristics between Nocdurna and Meclomen</p> <p><i>Rationale:</i> Although Nocdurna and Meclomen have the same word shape. The two products begin with different letters, ‘N’ vs ‘M’. In addition, although the fourth letter in both names (‘d’ vs ‘l’) is an upstroke, and gives each name its distinct shape, the letter ‘d’ has a rounded shape compared to the letter ‘l’ and gives the name Nocdurna a different visual appearance. The ending letter string for both names (‘urna’ vs. ‘omen’) also has a different visual appearance.</p> <p style="text-align: center;">N o c d u r n a M e c l o m e n</p> <p>In addition to the orthographic differences, medication errors are unlikely to occur due to differing product characteristics:</p> <p>Frequency of administration (once daily at bedtime vs. three to six times per day)</p> <p>Although both are oral (sublingual vs. oral), prescribers may provide additional instructions for use, such as SL, sublingually or place under the tongue for Nocdurna which will also help differentiate the two products.</p>

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22517	ORIG-1	FERRING PHARMACEUTICA LS INC	NOCDURNA

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