CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208437Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	November 13, 2017
Application Type and Number:	NDA 208437
Product Name and Strength:	Lonhala Magnair (glycopyrrolate) solution for Inhalation, 25 mcg
Product Type:	Drug-Device Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sunovion Respiratory Development Inc
Panorama #:	2017- 18604471
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Sarah K. Vee, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Lonhala Magnair, which was found unacceptable under NDA 208437 on September 8, 2017.[a] The proposed proprietary name, Lonhala Magnair, was found to be vulnerable to medication errors due to confusion with another product, Linhaliq***, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Lonhala Magnair, was dependent upon which underlying application was approved first.

We note that the goal date for NDA 208437 is December 15, 2017, whereas the goal date of underlying application for Linhaliq*** is (b) (4) . Thus, the applicant resubmitted the proposed proprietary name, Lonhala Magnair, for review.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The November 3, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, DMEPA evaluated the status of the underlying application of the conflicting name, Linhaliq***. We determined the goal date of underlying application for Linhaliq*** is (b) (4) . Therefore, if the proposed proprietary name, Lonhala Magnair, is granted approval under NDA 208437 on or before the December 15, 2017 PDUFA goal date for the application, this application approval will precede approval of the application with the conflicting proposed name, Linhaliq***.

Based upon our safety assessment of the proposed proprietary name, Lonhala Magnair, the application goal date for NDA 208437, and the status of the underlying application for Linhaliq***, we find Lonhala Magnair conditionally acceptable.

2.2 Communication of DMEPA's Analysis

DMEPA communicated our findings to the Division of the Pulmonary, Allergy and Rheumatology Products (DPARP) via e-mail on November 13, 2017.

3 CONCLUSIONS

We conclude that the proposed proprietary name, Lonhala Magnair, is acceptable. If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

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[a]Abraham, S. Proprietary Name Review for Lonhala Magnair (NDA 208437). 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); 2017 Sept 8, Panorama No. 15712077

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 27, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

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.

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/s/

SHERLY ABRAHAM
11/13/2017

SARAH K VEE
11/13/2017

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

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Date of This Review:	September 8, 2017
Application Type and Number:	NDA 208437
Product Name and Strength:	Lonhala Magnair (glycopyrrolate) solution for Inhalation, 25 mcg
Product Type:	Drug-Device Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sunovion Respiratory Development Inc
Panorama #:	2017- 15712077
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Sarah K. Vee, Pharm.D.
DMEPA Associate Director:	Mishale Mistry, PharmD, MPH
DMEPA Director:	Todd Bridges, RPh

1 INTRODUCTION

This memorandum is to amend the previous decision regarding the acceptability of the proposed proprietary name, Lonhala Magnair, which was found conditionally acceptable under IND 110663 on May 19, 2016[a] and NDA 208437 on August 18, 2016[b] . FDA issued a complete response (CR) for this application on May 26, 2017. On June 15, 2017, Sunovion Respiratory Development Inc resubmitted their NDA application. On June 16, 2017, they resubmitted their proprietary name for our review and submitted an amendment on June 19, 2017 to correct the spelling of the proposed proprietary name. We note that a conflict exists with another similar pending proposed proprietary name that is currently under review.

2 DISCUSSION

DMEPA had previously reviewed the proposed proprietary name, Lonhala Magnair, under IND 110663 and NDA 208437 and issued a ***CONDITIONALLY ACCEPTABLE*** letter for this name. Since that time, we have identified a conflict with another pending proposed proprietary name that is currently under review. The root name of the proposed name Lonhala Magnair, Lonhala, could result in medication errors due to confusion with Linhaliq***. Our evaluation of this name pair has altered our previous conclusion regarding the acceptability of the proposed proprietary name. The rationale for the risk of confusion is described below.

Lonhala Magnair vs. Linhaliq*

The root name of the proposed name, Lonhala Magnair, may be confused with another product that is currently under review, Linhaliq*** (ciprofloxacin dispersion for inhalation), due to orthographic and phonetic similarities as well as overlap in product characteristics.

Orthographically, the root name Lonhala and Linhaliq*** are similar in length (seven letters vs. eight letters). Both names have similar prefixes (‘Lon’ vs. ‘Lin’) and contain the identical infixes (‘hal’). The beginning letters of the suffixes (‘a’ vs. ‘i’) may appear similar when scripted. We note that Linhaliq*** has a downstroke letter ‘q’ at the end of the name, which is absent in Lonhala; however, given the orthographic similarity of the rest of the names, this may not provide for adequate differentiation.

The phonetic similarity between this name pair stems from the fact that both names contain three syllables with an identical syllable pattern of 2-1-3. The first syllable of this name pair is nearly identical, ‘Lon’ vs. ‘Lin,’ because both begin with /l/ and end with /n/, and the vowels ‘o’ vs. ‘i’ may not provide sufficient phonetic differences. The second syllables of this name pair are

[a]Abraham, S. Proprietary Name Review for Lonhala Magnair (IND 110663). 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); 2016 May 19, Panorama No. 2706431

[b]Abraham, S. Proprietary Name Review for Lonhala Magnair (NDA 208437). 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); 2016 Aug 18, Panorama No. 9421174

nearly identical, 'hah' vs. 'hale,' as the vowel 'a' can be pronounced either as /ə/ as in hah' or /e/ as in hale in either name, thus providing phonetic overlap in this second syllable. We acknowledge that the third syllables, 'luh' vs. 'ick,' are different; however, this may not provide adequate differentiation between the names given the overwhelming similarities in the rest of the name.

We acknowledge the modifier "Magnair" is included in the name, Lonhala Magnair; however, we know from postmarketing experience that modifiers can be omitted or overlooked.[c]

This similarity of this name pair is supported by the FDA Phonetic and Orthographic Computer Analysis (POCA) software, which calculated a combined match score of 70%, indicating that the name pair is highly similar[d].

In addition to the orthographic and phonetic similarities between this name pair, Lonhala Magnair and Linhaliq *** also have overlapping product characteristics. Both products share the route of administration (*oral inhalation*), overlapping dose (*1 vial or use as directed*), and similar dosage forms (*solution for inhalation vs. aqueous dispersion for inhalation*). Although the strengths will differ (*25 mcg vs. 189 mg/6 mL*), we note that both products will be available in a single strength. Thus, the strength may not be included on a prescription to serve as a differentiating factor than can minimize the risk for error. There are postmarketing wrong drug error reports involving single strength products which further support the potential for confusion with this name pair. This was seen in the case of the vaginal cream Clindesse (clindamycin phosphate 2%) that was confused with the topical swab Clindets (clindamycin phosphate 1%)[e] and the ophthalmic drug Durezol (difluprednate ophthalmic emulsion 0.05%) that was confused for a topical wart remover Durasal (salicylic acid 26%)[f]. In addition, we have found that difference in the frequency of administration (*twice daily vs. once a day*) alone may not be sufficient to prevent errors as was seen in the case of Razadyne (galantamine), a medication for Alzheimer's disease which is normally administered twice a day, which was confused with Rozerem (ramelteon), a sleep aid which is normally administered as one tablet within 30 minutes of going to bed[g].

Based on the orthographic and phonetic similarities, as well as the overlapping product characteristics between the proposed root name Lonhala and the proposed name Linhaliq***, we conclude that there is a risk of wrong drug error if both names co-exist in the market. Therefore, we find the proposed name Lonhala Magnair unacceptable.

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[c] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.
[d] POCA search conducted on August 1, 2017. POCA tool updated to incorporate a revised orthographic algorithm
[e] Institute for Safe Medication Practices. Voice mail: What's that you said? ISMP Med Saf Alert Community/Ambulatory Care. 2008; 7(12): 1-6.
[f] "FDA Alerts Pharmacists and Health Care Professionals to the Potential for Injury when Dispensing the Similar-Sounding Drugs Durezol and Durasal". FDA Safety Alert. December 28, 2011. http://www.fda.gov/Drugs/DrugSafety/ucm285235.htm
[g] Institute for Safe Medication Practices. Safety Briefs: Rozerem – Razadyne mix-ups. ISMP Med Saf Alert Community/Ambulatory Care. 2006; 5(2): 1-4.

We note that this decision differs from our previous decision regarding the acceptability of the proposed proprietary name. However, when Lonhala Magnair, was previously evaluated, the proposed proprietary name, Linhaliq*** was not yet submitted for review by the Agency.

2.1 Communication of DMEPA's Analysis

DMEPA communicated our findings to the Division of the Division of the Pulmonary, Allergy and Rheumatology Products (DPARP) via e-mail on September 1, 2017.

3 CONCLUSIONS

The proposed proprietary name is not acceptable from a safety perspective. The proposed name is vulnerable to name confusion with Linhaliq***.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO THE APPLICANT

Your proposed name was found conditionally acceptable on May 27, 2016 under IND 110663 and on August 25, 2016 under NDA 208437. Since that time, we have determined that your proposed proprietary name, Lonhala Magnair, could result in medication errors due to confusion with another product that is currently under review. Therefore, the ultimate acceptability of your proposed proprietary name, Lonhala Magnair, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name of Lonhala Magnair, you will be requested to submit another name.

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/s/

SHERLY ABRAHAM
09/08/2017

SARAH K VEE
09/08/2017

MISHALE P MISTRY
09/08/2017

TODD D BRIDGES
09/08/2017

PROPRIETARY NAME MEMORANDUM

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

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Date of This Review:	August 18, 2016
Application Type and Number:	NDA 208437
Product Name and Strength:	Lonhala Magnair (glycopyrrolate) Solution for Inhalation 25 mcg
Product Type:	Drug-Device Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sunovion Respiratory Development Inc
Panorama #:	2016- 9421174
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Mishale Mistry, Pharm.D., MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Lonhala Magnair, which was found conditionally acceptable under IND 110663 on May 19, 2016.[1]

We note that there is a change in the product strength and dose. We previously reviewed the product strength as 50 mcg and dose of 1 vial (50 mcg) administered twice daily using the associated device. Under NDA 208437, the proposed strength is 25 mcg and the proposed dose is 1 vial (25 mcg) administered twice daily using the associated device. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of the Pulmonary, Allergy and Rheumatology Products (DPARP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary of name, DMEPA evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. We also evaluated previously identified names taking into account the change in product strength and dose. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The August 17, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable from a promotional and safety perspective.

If you have any questions or need clarifications, please contact Michael Sinks, OSE project manager, at (240) 402-2684.

3.1 COMMENTS TO THE APPLICANT

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

[1]Abraham, S. Proprietary Name Review for Lonhala Magnair (IND 110663). 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); 2016 05 019, Panorama No. 9421174

If any of the proposed product characteristics as stated in your July 29, 2016 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)**

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/s/

SHERLY ABRAHAM
08/18/2016

MISHALE P MISTRY
08/22/2016