CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215422Orig1s000

OTHER REVIEW(S)

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

Date of This Memorandum:	November 23, 2021
Requesting Office or Division:	Division of Neurology 1 (DN 1)
Application Type and Number:	NDA 215422
Product Name and Strength:	Lyvispah (baclofen) oral granules, 5 mg, 10 mg, 20 mg
Applicant/Sponsor Name:	Saol Therapeutics Research Limited (Saol)
OSE RCM #:	2021-259-3
DMEPA 2 Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA 2 Acting Team Leader:	Stephanie DeGraw, PharmD

1 PURPOSE OF MEMORANDUM

Saol submitted revised container labels and carton labeling on November 19, 2021 for Lyvispah (baclofen) oral granules. The Division of Neurology 1 (DN 1) requested that we review the revised labeling (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 CONCLUSION

Saol implemented our recommendation and we have no additional recommendations at this time.

[a] Morris, C. Label and Labeling Review MEMO for baclofen granules (NDA 215422). Silver Spring (MD): FDA, CDER, OSE, DMEPA2 (US); 2021 NOV 18. RCM No.: 2021-259-2.

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/s/

JOHN C MORRIS
11/23/2021 07:37:34 AM

STEPHANIE L DEGRAW
11/23/2021 09:43:17 AM

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

Date of This Memorandum:	November 18, 2021
Requesting Office or Division:	Division of Neurology 1 (DN 1)
Application Type and Number:	NDA 215422
Product Name and Strength:	Lyvispah (baclofen) oral granules, 5 mg, 10 mg, 20 mg
Applicant/Sponsor Name:	Saol Therapeutics Research Limited (Saol)
OSE RCM #:	2021-259-2
DMEPA 2 Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA 2 Acting Team Leader:	Stephanie DeGraw, PharmD

1 PURPOSE OF MEMORANDUM

Saol submitted revised container labels and carton labeling on November 16, 2021 for Lyvispah (baclofen) oral granules. The Division of Neurology 1 (DN 1) requested that we review the revised labeling (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 ASSESSMENT

Saol implemented our recommendation to add the conditionally approved proprietary name, Lyvispah, to the labeling; however, we find it does not satisfy 21 CFR 201.10(g)(2). Additionally, Saol provided justification for not including a linear barcode on the container labels, which we find acceptable.

3 CONCLUSION

The revised carton labeling and container labels can be improved to satisfy 21 CFR 201.10(g)(2). We provide our recommendation in Section 3 for Saol.

[a] Morris, C. Label and Labeling Review for baclofen granules (NDA 215422). Silver Spring (MD): FDA, CDER, OSE, DMEPA2 (US); 2021 OCT 29. RCM No.: 2021-259-1.

4 RECOMMENDATIONS FOR SAOL THERAPEUTICS RESEARCH LIMITED

We recommend the following be implemented prior to approval of this NDA:

Identified Issues and Recommendations for Saol Therapeutics Research Limited (entire table to be conveyed to Applicant)		
IDENTIFIED ISSUE	**RATIONALE FOR CONCERN**	**RECOMMENDATION**
Container Labels and Carton Labeling – General		
The established name lacks prominence commensurate with the proprietary name.	The established name is not at least half the size of the proprietary name.	Increase the prominence of the established name taking into account all pertinent factors, including typography, layout, contrast, and other printing features in accordance with 21 CFR 201.10(g)(2).

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JOHN C MORRIS
11/18/2021 12:15:23 PM

STEPHANIE L DEGRAW
11/18/2021 12:35:24 PM

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

PATIENT LABELING REVIEW

Date:	November 3, 2021
To:	Taura Holmes, PharmD, MS, GWCPM Senior Regulatory Project Manager **Division of Neurology I (DN1)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)** Marcia Williams, PhD Team Leader, Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Mary Carroll, BSN, RN Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Domenic D'Alessandro, PharmD, MBA, BCPS, CDCES Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI) and Instructions for Use (IFU)
Drug Name (established name):	LYVISPAH (baclofen)
Dosage Form and Route:	oral granules
Application Type/Number:	NDA 215422
Applicant:	Saol Therapeutics Research Limited through the authorized U.S. agent Saol Therapeutics Inc.

1 INTRODUCTION

On January 22, 2021, Saol Therapeutics Research Limited through the authorized U.S. agent Saol Therapeutics Inc. submitted for the Agency's review an original New Drug Application (NDA) 215422 LYVISPAH (baclofen) oral granules. The proposed indication is to treat spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a request by the Division of Neurology I (DN1) on September 29, 2021 for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) and Instructions for Use (IFU) for LYVISPAH (baclofen) oral granules.

2 MATERIAL REVIEWED

- Draft LYVISPAH (baclofen) PPI and IFU received on January 22, 2021 and received by DMPP on October 27, 2021.
- Draft LYVISPAH (baclofen) PPI and IFU received on January 22, 2021and received by OPDP on November 3, 2021.
- Draft LYVISPAH (baclofen) Prescribing Information (PI) received on January 22, 2021, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on October 27, 2021.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss. We reformatted the PPI and IFU document using the Arial font, size 10.

In our collaborative review of the PPI and IFU we:

- simplified wording and clarified concepts where possible
- ensured that the PPI and IFU are consistent with the Prescribing Information (PI)
- removed unnecessary or redundant information
- ensured that the PPI and IFU are free of promotional language or suggested revisions to ensure that it is free of promotional language

- ensured that the PPI and IFU meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)

4 CONCLUSIONS

The PPI and IFU are acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DMPP and OPDP on the correspondence.
- Our collaborative review of the PPI and IFU are appended to this memorandum. Consult DMPP and OPDP regarding any additional revisions made to the PI to determine if corresponding revisions need to be made to the PPI and IFU.

Please let us know if you have any questions.

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/s/

MARY E CARROLL
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DOMENIC G DALESSANDRO
11/04/2021 07:38:15 AM

MARCIA B WILLIAMS
11/04/2021 07:42:25 AM

LASHAWN M GRIFFITHS
11/04/2021 09:01:30 AM

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

Date of This Memorandum:	October 29, 2021
Requesting Office or Division:	Division of Neurology 1 (DN 1)
Application Type and Number:	NDA 215422
Product Name and Strength:	Lyvispah (baclofen) oral granules, 5 mg, 10 mg, 20 mg
Applicant/Sponsor Name:	Saol Therapeutics Research Limited
OSE RCM #:	2021-259-1
DMEPA 2 Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA 2 Acting Team Leader:	Stephanie DeGraw, PharmD

1 PURPOSE OF MEMORANDUM

The Applicant submitted revised Prescribing Information (PI), container labels, and carton labeling received on October 21, 2021 for Lyvispah (baclofen) oral granules. Division of Neurology 1 (DN 1) requested that we review the revised container labels and carton labeling for Lyvispah (baclofen) oral granules (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 CONCLUSION

The Applicant implemented all of our recommendations for the container labels and carton labeling; however, the revised carton labeling and container labels can be improved from a medication error perspective. We provide our assessment and recommendation in Section 3, below.

3 RECOMMENDATIONS FOR SAOL THERAPEUTICS RESEARCH LIMITED

We recommend the following be implemented prior to approval of this NDA:

[a] Morris, C. Label and Labeling Review for baclofen granules (NDA 215422). Silver Spring (MD): FDA, CDER, OSE, DMEPA2 (US); 2021 JUL 12. RCM No.: 2021-259.

Identified Issues and Recommendations for Saol Therapeutics Research Limited (entire table to be conveyed to Applicant)		
IDENTIFIED ISSUE	**RATIONALE FOR CONCERN**	**RECOMMENDATION**
Container Labels and Carton Labeling – General		
The "TRADENAME" placeholder may be updated with the conditionally acceptable proprietary name, Lyvispah.	We refer to the Proprietary Name Decision Letter dated October 28, 2021 finding the proposed proprietary name, Lyvispah, conditionally acceptable.	We recommend you replace the placeholder "TRADENAME" with the proprietary name "Lyvispah" on all applicable areas of the labels and labeling.
Container Labels		
We note you moved the linear barcode from the container label to the carton labeling.	A linear barcode is not required on the container labels; however, the drug barcode is often used as an additional verification before drug administration in the hospital setting. Therefore, it is an important safety feature that should be part of the container label whenever possible.	We request you add a linear barcode to each individual stick pack. We recommend you position the linear barcode parallel to the length of the packaging to improve the scanability of the barcode. In addition, the barcode should be surrounded by sufficient white space to allow scanners to correctly read the barcode.

4 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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JOHN C MORRIS
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STEPHANIE L DEGRAW
10/29/2021 04:16:01 PM

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: October 29, 2021

To: Laura Jawidzik, MD, Clinical Team Leader
Division of Neurology-1 (DN-1)

Taura Holmes, PharmD, MS, GWCPM, Regulatory Project Manager, (DN-1)

Tracy Peters, PharmD, Associate Director for Labeling, (DN-1)

From: Domenic D'Alessandro, PharmD, MBA, BCPS, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Aline Moukhtara, RN, MPH, Team Leader, OPDP

Subject: OPDP Labeling Comments for LYVISPAH (baclofen) oral granules

NDA: 215422

In response to DN-1's consult request dated September 21, 2021, OPDP has reviewed the proposed product labeling (PI) and carton and container labeling for the original NDA submission for LYVISPAH (baclofen) oral granules.

PI: OPDP's comments on the proposed labeling are based on the draft labeling received by electronic mail from DN-1 (Taura Holmes) on October 27, 2021, and are provided below.

Carton and Container Labeling: OPDP has reviewed the attached proposed carton and container labeling submitted by the Sponsor to the electronic document room on October 21, 2021, and we do not have any comments.

Thank you for your consult. If you have any questions, please contact Domenic D'Alessandro at (301) 796-3316 or domenic.dalessandro@fda.hhs.gov.

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/s/

DOMENIC G DALESSANDRO
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LABEL AND LABELING 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:	July 12, 2021
Requesting Office or Division:	Division of Neurology 1 (DN 1)
Application Type and Number:	NDA 215422
Product Name and Strength:	baclofen[a] granules, 5 mg, 10 mg, 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Saol Therapeutics Research Limited
FDA Received Date:	January 22, 2021, April 20, 2021
OSE RCM #:	2021-259
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Acting Team Leader:	Celeste Karpow, PharmD, MPH

[a] Proposed proprietary name, (b) (4), is currently under review.

1 REASON FOR REVIEW

As part of the approval process for baclofen granules, the Division of Neurology 1 (DN 1) requested that we review the proposed Prescribing Information (PI), Medication Guide (MG), Instructions for Use (IFU), carton labeling, and container labels for areas of vulnerability that may lead to medication errors.

2 REGULATORY HISTORY

NDA 215422 is a 505(b)(2) NDA. The listed drug product is Lioresal, NDA 017851, and the reference standard is baclofen tablets, ANDA 072235.

3 MATERIALS REVIEWED

Table 1. Materials Considered for this Label and Labeling Review

Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B
ISMP Newsletters*	C (N/A)
FDA Adverse Event Reporting System (FAERS)*	D (N/A)
Other	E (N/A)
Labels and Labeling	F

N/A=not applicable for this review

*We do not typically search FAERS or ISMP Newsletters for our label and labeling reviews unless we are aware of medication errors through our routine postmarket safety surveillance

4 CONCLUSION AND RECOMMENDATIONS

The proposed PI, MG, IFU, carton labeling, and container labelsmay be improved to promote the safe use of this product from a medication error perspective. We provide the identified medication error issues, our rationale for concern, and our proposed recommendations to minimize the risk for medication error in Section 5 for the Division and in Section 6 for Saol Therapeutics Research Limited.

5 RECOMMENDATIONS FOR DN1

Table 2. Identified Issues and Recommendations for Division of Neurology 1 (DN 1)			
	IDENTIFIED ISSUE	**RATIONALE FOR CONCERN**	**RECOMMENDATION**
Highlights of Prescribing Information – Dosage and Administration			
1.	The following statements (b) (4)	May increase the risk for wrong technique administration errors.	We recommend rewording the following statements: to read: • The granules may be taken by mouth with or without water. (2.2) • The granules may be mixed with liquid or soft food for administration within 2 hours. (2.2) • The granules may be mixed and administered via enteral feeding tubes. (2.2) or similar.
Full Prescribing Information – Section 3 Dosage Forms and Strengths and 16 How Supplied/Storage and Handling			
1.	We note the granules are strawberry flavored.	May increase the risk for accidental exposure or overdose in children.	We recommend the review team ensures the container aligns with current child-resistant closure recommendations.
Medication Guide and Instructions for Use			
1.	There are four potential oral administration techniques: swallow granules, swallow granules with water, add to a small volume of liquid, and mix in soft food.	The presentation and organization of the four oral administration techniques can be improved for clarity and readability.	We recommend you consider reorganizing the MG and IFU to highlight the four administration techniques. As an example, for the MG, consider separating the four

	[redacted] (b) (4)		administration techniques as separate bullets. As an example, for the IFU, separate "How to take" into the following sections: how to open, oral administration techniques, feeding tube administration.
Instructions for Use			
1.	There are two potential routes of administration, oral and feeding tube; however, the first line states [redacted] (b) (4)	Do not align with the intended use of the product.	We recommend you revise the statement [redacted] (b) (4) to read [redacted] (b) (4) and relocate it after the instructions for opening the container.
2.	The text instructing the user how to open the container states [redacted] (b) (4); however, the image does not clearly align with the text.	The text and image should align in content.	We recommend you consider revising the image to include a full display of the container, which also contains a representation of the direction to tear open.

6 RECOMMENDATIONS FOR SAOL THERAPEUTICS RESEARCH LIMITED

Table 3. Identified Issues and Recommendations for Saol Therapeutics Research Limited (entire table to be conveyed to Applicant)

	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Container Labels and Carton Labeling – General			
1.	We note the granules are strawberry flavored and supplied in 'stick packs' that may resemble candy.	We are concerned about the risk for accidental exposure or overdose in children.	We recommend you consider the risks of accidental exposure or overdose in children given your proposed packaging configuration.

Table 3. Identified Issues and Recommendations for Saol Therapeutics Research Limited (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	**RATIONALE FOR CONCERN**	**RECOMMENDATION**
2.	The proposed proprietary name, (b) (4), was denied.	You have submitted an alternate proprietary name, (b) (4), which is currently under review.	Denote the proprietary name placeholder as "Tradename" until a proprietary name has been granted conditional approval. We recommend you present "Tradename" in your intended artistic design.
3.	The route of administration statement is not present.	May increase the risk for wrong route of administration errors, since the dosage form is granules, the route of administration is not assumed.	We recommend you add the route of administration to the principal display panel (PDP).
4.	The expiration date format is 00/0000 on the container labels, and MM/DD/YYYY on the carton labeling.	As currently presented, the format for the expiration date is unclear.	Please clarify the intended format for the expiration date and whether the month will be displayed in alphabetical or numerical characters, and ensure the same format is used on the carton labeling and container labels. The Drug Supply Chain Security Act (DSCSA) guidance on product identifiers "recommends that the human-readable expiration date on the drug package label include a year, month, and non-zero day in YYYY-MM-DD format if using only numerical characters or in YYYY-MMM-DD if using alphabetical characters to represent the month. If there are space limitations on the drug package, the human-readable text may include only a year

Table 3. Identified Issues and Recommendations for Saol Therapeutics Research Limited (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	**RATIONALE FOR CONCERN**	**RECOMMENDATION**
			and month, expressed as YYYY-MM if using only numerical characters or YYYY-MMM if using alphabetical characters to represent the month. FDA recommends using a slash or a hyphen to separate the portions of the expiration date."
5.	The usual dose statements can be improved.	The language is inconsistent with the Prescribing Information.	To ensure consistency with the Prescribing Information, revise the usual dose statements to read "Recommended Dosage: See prescribing information."
Container Labels			
1.	The orientation and placement of the linear barcode can be improved.	We are concerned the barcode will may not scan due to package curvature or folding.	Consider reorienting and relocating the linear barcode to a position parallel to the length of the packaging to improve the scanability of the barcode. In addition, the barcode should be surrounded by sufficient white space to allow scanners to correctly read the barcode in accordance with 21 CFR 201.25(c)(i).
2.	As currently presented, the storage statement does not contain a unit of measure after each temperature.	May increase the risk for improper storage medication errors.	We recommend you revise the storage statement to read "Store at 20°C to 29°C (68°F to 77°F)."
Carton Labeling			
1.	The proposed labeling submitted on January 22, 2021 contains a Medication Guide (MG);	Does not comply with 21 CFR 208.24(d).	If a MG will be part of the approved labeling, then add the following statement to the PDP "Dispense the enclosed

Table 3. Identified Issues and Recommendations for Saol Therapeutics Research Limited (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	**RATIONALE FOR CONCERN**	**RECOMMENDATION**
	however, the MG statement is not presented on the PDP.		(b) (4)
2.	As currently presented, there is no linear barcode.	Does not comply with 21 CFR 201.25(c)(2).	The drug barcode is often used as an additional verification; therefore, it is an important safety feature that should be part of the label whenever possible. Therefore, we request you add the product's linear barcode as required per 21CFR 201.25(c)(2).
3.	As currently presented, the storage statement contains the symbol "-" and does not contain a unit of measure after each temperature.	May increase the risk for improper storage medication errors.	We recommend you revise the storage statement to read Store at 20°C to 29°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). (See USP Controlled Room Temperature)."
Carton labeling – Commercial and Professional Samples			
4.	There are five total administration techniques; however, only four administration techniques are described. The following administration technique is missing: add to a small volume of liquid. Additionally, the note to use the mixed product within 2 hours is absent.	As presented, the directions for use are incomplete, which can be improved for clarity to reduce the risk for wrong technique or expired medication errors.	We recommend you add language to item 5 that includes adding to a small volume of liquid. Additionally, add a statement indicating the product prepared using these techniques should be used within 2 hours. Lastly, consider adding the title "Directions for Use" at the top for completeness.

APPENDICES: METHODS & RESULTS FOR EACH MATERIAL REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 4 presents relevant product information for baclofen granules that Saol Therapeutics Research Limited submitted on January 22, 2021.

Table 4. Relevant Product Information for Listed Drug and baclofen granules

Product Name	**Lioresal**	Baclofen
Initial Approval Date	11/22/1977	N/A
Active Ingredient	baclofen	Baclofen
Indication	Baclofen tablets are useful for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity
Route of Administration	Oral	Oral
Dosage Form	Tablets	Granules
Strength	10 mg, 20 mg	5 mg, 10 mg, 20 mg
Dose and Frequency	The determination of optimal dosage requires individual titration. Start therapy at a low dosage and increase gradually until optimum effect is achieved (usually between 40 to 80 mg daily). The following dosage titration schedule is suggested: 5 mg t.i.d. for 3 days 10 mg t.i.d. for 3 days 15 mg t.i.d. for 3 days 20 mg t.i.d. for 3 days Thereafter additional increases may be necessary but the total daily dose should not exceed a	Initiate with a low dosage, preferably in divided doses, administered orally. The following gradually increasing dosage regimen is suggested, but should be adjusted based on clinical response and tolerability: 5mg three times a day for three days 10mg three times a day for three days 15mg three times a day for three days 20mg three times a day for three days.

	maximum of 80 mg daily (20 mg q.i.d.). The lowest dose compatible with an optimal response is recommended. If benefits are not evident after a reasonable trial period, patients should be slowly withdrawn from the drug	Additional increases may be necessary up to the maximum recommended dosage of 80mg daily (20mg four times a day).
How Supplied	Bottles containing 100 tablets [redacted]	Carton containing 90 stick packs
Storage	[redacted]	Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room temperature].
Container Closure	[redacted]	[redacted] or stick pack,

APPENDIX B. PREVIOUS DMEPA REVIEWS

On May 11, 2021, we searched for previous DMEPA reviews relevant to this current review using the terms, baclofen, baclofen granules, and NDA 215422. Our search did not identify any previous reviews.

APPENDIX F. LABELS AND LABELING

F.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[b] along with postmarket medication error data, we reviewed the following labels and labeling submitted by Saol Therapeutics Research Limited.

- Container labels received on January 22, 2021
- Carton labeling received on January 22, 2021
- Professional Sample Carton Labeling received on January 22, 2021
- Prescribing Information (Image not shown), received on April 20, 2021, available from \\CDSESUB1\evsprod\nda215422\0004\m1\us\114-label\1141-draft-label\proposed-tc.docx
- Medication Guide and Instructions for Use, received on January 22, 2021, available from \\CDSESUB1\evsprod\nda215422\0001\m1\us\114-label\1141-draft-label\proposed.docx

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

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/s/

JOHN C MORRIS
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07/12/2021 12:41:26 PM

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 4/14/2021

TO: Division of Neurology I (DN I)
Office of Neuroscience (ON)

FROM: Division of New Drug Study Integrity (DNDSI)
Office of Study Integrity and Surveillance (OSIS)

SUBJECT: **Decline to conduct an on-site inspection**

RE: NDA 215422

The Division of New Drug Study Integrity (DNDSI) within the Office of Study Integrity and Surveillance (OSIS) determined that inspections are not warranted at this time for the sites listed below. The rationale for this decision is noted below.

Rationale

(b) (4) The clinical and analytical inpections were conducted in (b) (4) (b) (4), which falls within the surveillance interval. The inspections were conducted under the following submissions: (b) (4).

Syneos Health, Inc. (Montreal): The Office of Regulatory Affairs (ORA) inspected the site in July 2019, which falls within the surveillance interval. The inspection was conducted under the following submissions: (b) (4).

The final classification for the inspections was No Action Indicated (NAI).

Therefore, based on the rationale provided above, inspections are not warranted at this time.

Inspection Sites

Facility Type	Facility Name	Facility Address
Clinical	(b) (4)	
Clinical	Syneos Health, Inc.	5160, boul. Decarie, Suite 800, Montreal, Quebec, Canada
Analytical	(b) (4)	

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