

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

209531Orig1s000

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)

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Date of This Review:	November 2, 2016
Application Type and Number:	NDA 209531
Product Name and Strength:	Spinraza (nusinersen) injection 12 mg/5 mL 2.4 mg/mL
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Biogen, Inc.
Panorama #:	2016-10540345
DMEPA Primary Reviewer:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Lolita White, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Spinraza (nusinersen), which was found conditionally acceptable under IND 110011 on August 6, 2015.^a We note that all 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 Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 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 October 7, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.2.1 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Spinraza (nusinersen) will be available in the strength of 2.4 mg/mL. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS)^b database to identify any names with an overlap in strength and potential orthographic, spelling, and phonetic similarities with Spinraza. The October 13, 2016 eDRLS search identified fifty unique names, none of which are likely to be confused with the proposed name, Spinraza. (See Appendix I).

We note that our previous name review of Spinraza did not use eDRLS database as a search tool, thus we provide updates in this current review.

Table 1A. eDRLS Search Results ^c	POCA Score (%)
N/A	

^a Myers, D. Proprietary Name Review for Spinraza (IND 110011). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 AUG 06. Panorama No. 2015-80225.

^c eDRLS search conducted on October 13, 2016.

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, Spinraza, is acceptable from a safety perspective.

If you have any questions or need clarifications, please contact Corwin Howard, OSE project manager, at 240-402-8654.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 23, 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>)

USAN Stems List contains all the recognized USAN stems.

2. 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.

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	A.H.C. C-TONER
2.	ACT Dry Mouth Anticavity Fluoride
3.	Advance White
4.	Advance White Extreme Whitening
5.	AHC Whitening Special Gen Solution
6.	AIM
7.	AIM Cavity Protection
8.	AIM TARTAR CONTROL
9.	AIM Whitening
10.	Albuterol Sulfate
11.	BAROX
12.	BriteSmile
13.	Cell Renew Bio Special Set
14.	Cellpium premiumEX hybrid toner
15.	clear days ahead
16.	CLOSE UP
17.	Colgate
18.	Colgate Max Clean Effervescent Mint Fluoride
19.	Colgate Proclinical - Clean Mint
20.	COLGATE PROCLINICAL - Sparkling Mint
21.	Colgate Sparkling White CinnaMint Fluoride
22.	Colgate Triple Action Original Mint Fluoride
23.	Colgate Triple Action Original Mint Fluoride
24.	Colgate UltraBrite Advanced Whitening Anticavity Fluoride Clean Mint
25.	Complete Care
26.	Complete Care Tartar Control
27.	DAMOE THERAPY TONIC
28.	Dental Care Advance Cleaning
29.	Dinosaur Gel Toothpaste

No.	Name
30.	EASTER SCALP
31.	G9 Whitening
32.	GINSENG ROYAL SILK
33.	GINSENG ROYAL SILK TONER
34.	HAIRFILL SCALP HAIR ESSENTIAL
35.	Kids Crest
36.	Lasting Foundation SPF 12
37.	Mentadent
38.	NUTRITIOUS
39.	Orajel
40.	PAIN RELIEVER
41.	Pepsodent Complete Care
42.	Peroxie Care Tartar Control
43.	Plak Smacker
44.	Rembrandt Intense Stain
45.	Shark Toothpaste
46.	Shopkins Brush Buddies
47.	Sparkle Fresh Anticavity
48.	Sucrets
49.	Ultra Whitening First Essence
50.	Walgreens Scooby Doo Fluoride Gel Toothpaste

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/s/

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11/02/2016

LOLITA G WHITE
11/02/2016