CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212535Orig1s000

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:	September 5, 2019
Application Type and Number:	NDA 212535
Product Name and Strength:	Nouress (cysteine hydrochloride, USP) Injection, 500 mg/10 mL (50 mg/mL)
Total Product Strength:	50 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Avadel Legacy Pharmaceuticals, LLC
Panorama #:	2019-32766541
DMEPA Safety Evaluator:	Lissa C. Owens, PharmD
DMEPA Team Leader:	Idalia E. Rychlik, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Nouress, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Avadel Legacy Pharmaceuticals, LLC submitted an external name study, conducted by (b) (4), for this proposed proprietary name.

1.1 REGULATORY HISTORY

Avadel previously submitted the proposed proprietary name, previous proposed name (b) (4) *** on March 18, 2019. However, we found the previous proposed name (b) (4) *** unacceptable due to similarity in spelling with the proprietary name, (b) (4) under NDA 212535 on June 12, 2019[a].

Thus, Avadel submitted the name, Nouress, for review on June 27, 2019.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 27, 2019.

- Intended Pronunciation: nur-es
- Active Ingredient: cysteine hydrochloride, USP
- Indication of Use: For use as an additive to amino acids solutions to meet nutritional requirements of neonates requiring total parenteral nutrition (TPN)
- Route of Administration: Intravenous Infusion
- Dosage Form: Injection
- Strength: 500 mg/10 mL (50 mg/mL)
- Dose and Frequency: For addition to amino acids solutions intended for use in neonates, it is recommended that NOURESS be added to the amino acids solution to provide cysteine at (b) (4)% of the total amino acids being supplied. Hence, a neonate receiving amino acids solutions at (b) (4) g/kg/day should be provided (b) (4) mg/kg/day of cysteine or (b) (4) mL/kg/day of NOURESS (b) (4). A neonate receiving 3 g/kg/day of amino acids should be provided (b) (4) mL/kg/day of NOURESS (b) (4).

  The amino acids admixture should then be aseptically diluted with appropriate caloric substrates calculated to supply the patient with adequate energy. The admixture should be refrigerated until ready for use and used within 24 hours of the time of mixing.
- How Supplied: 10 mL single dose vial (single and package of (b) (4) vials)
- Storage: Store at controlled room temperature 15°-30°C (59°-86°F) Do not freeze.

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[a] McMillan, T. Proprietary Name Review for (b) (4) (NDA 212535). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUN 12. Panorama No. 2019- 30148818

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Nouress would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Gastroenterology and Inborn Errors Products (DGIEP) concurred with the findings of OPDP's assessment for Nouress.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Nouress.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[b]

2.2.2 Components of the Proposed Proprietary Name

Avadel did not provide a derivation or intended meaning for the proposed proprietary name, Nouress, 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.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, July 12, 2019 e-mail, the Division of Gastroenterology and Inborn Errors Products (DGIEP) did not forward any comments or concerns relating to Nouress at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-seven practitioners participated in DMEPA's prescription studies for Nouress. 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. 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[c] identified 84 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

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[b] USAN stem search conducted on August 12, 2019.

[c] POCA search conducted on August 12, 2019 in version 4.3.

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