CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208700Orig1s000

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:	January 8, 2018
Application Type and Number:	NDA 208700
Product Name and Strength:	Lutathera (lutetium Lu 177 dotatate) Injection, 370 MBq/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Advanced Accelerator Applications USA Inc.
Panorama #:	2017-18841079
DMEPA Safety Evaluator:	Janine Stewart, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Lutathera, 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, Lutathera on November 9, 2015 under IND 077219 and on April 28, 2016 under NDA 208700. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Lutathera, acceptable on April 5, 2016 and again on May 26, 2016.[a,b] However, the Division of Oncology Products 2 (DOP2) issued a Complete Response (CR) for the application on December 19, 2016.

For the class 2 resubmission, the Applicant submitted the NDA on July 26, 2017, and submitted the proposed proprietary name, Lutathera, for review on November 8, 2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the November 8, 2017 proprietary name submission.

- **Intended Pronunciation:** Lou-Ta-Ther-a
- **Active Ingredient:** Lutetium Lu 177 dotatate
- **Indication of Use:** Treatment of somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.
- **Route of Administration:** Intravenous
- **Dosage Form:** Injection
- **Strength:** 370 MBq/mL
- **Dose and Frequency:** A cumulative dose of 29.6 GBq (maximum dose) divided into four- 30 minute intravenous infusions of 7.4 GBq at 8 (b) (4) week intervals (b) (4) to accommodate resolving toxicity. The product is administered with a concomitant infusion of an amino acid solution containing arginine and lysine.
- **How Supplied:** Ready-to-use, single-dose, (b) (4) mL vials containing 7.4 GBq of Lutathera. The product is shipped to the hospital (radiopharmacy) or nuclear medicine physician (b) (4)

[a] Stewart, J. Proprietary Name Review for Lutathera IND 077219. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Apr 05. RCM No.: 2015-1947595.

[b] Stewart, J. Proprietary Name Review for Lutathera NDA 208700. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 May 26. RCM No.: 2016-7757226.

[redacted]

- **Storage:** Store below [redacted] Store in its original packaging for radioprotection purposes. Vial radioactivity must be verified before infusion. Shelf life: Maximum 72 hours [redacted].
  The product must be stored according to national regulations concerning radioactive products and will be labeled with the cautionary statement.
- **Container and Closure Systems:** A single dose [redacted] mL vial, colorless Type I glass enclosed with a rubber stopper and sealed by an aluminum crimp. The vial is enclosed within a lead container with 12 mm shielding (inner dimensions: 33.4 x 69 mm [dia x H], outer dimensions: 57 x 93.7 mm [dia x H]). The lead container is green [redacted]. The lead container is sealed with [redacted] packaging tape and every container is also packed in [redacted] bags. These are leak proof, airtight and tamper evident. The bags are tested at [redacted] kPa.

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) and the Division of Oncology Products 2 (DOP2) concurred with the findings of OPDP's 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 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 in the current submission. However, the Applicant previously indicated in their request for proprietary name submission under the IND that the proposed name, Lutathera, is derived from Lutetium. 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.

[c] USAN stem search conducted on (November 17, 2017).

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