

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208169Orig1s000

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: 18 February 2015

Requesting Office or Division: Division of Gastroenterology and Inborn Error Products (DGIEP)

Application Type and Number: NDA 208169

Product Name and Strength: Xuriden (uridine triacetate) oral granules
2 gram, (b) (4), and (b) (4) packets

Product Type: Single Ingredient Product

Rx or OTC: Rx

Applicant/Sponsor Name: Wellstat Therapeutics Corporation

Submission Date: 20 January 2015

Panorama #: 2015-47663

DMEPA Primary Reviewer: Rhiannon Leutner, PharmD, MPH, MBA

DMEPA Team Leader: Jo Wyeth, PharmD

1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Xuriden under NDA 208169, which was found acceptable under IND (b) (4) and IND 118931² with the following proposed indications: uridine replacement therapy in patients with hereditary orotic aciduria (HOA), (b) (4)

(b) (4) Wellstat filed NDA 208169 on 8 January 2015 for Xuriden as replacement uridine therapy in pediatric patients with HOA. NDA 208169 proposes the addition of a 2 gram packet (b) (4). All other product characteristics remain the same.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, we conducted a gap analysis and searched the POCA database to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review # 2014-17316². We 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 addition of a 2 gram packet. Additionally, we searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates.

Our re-assessment did not identify any new names that represent a potential source of drug name confusion. The 25 June 2014 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

The proposed proprietary name, Xuriden, is acceptable from both a promotional and safety perspective under the NDA 208169.

If you have further questions or need clarifications, please contact Aleksander Winiarski, OSE Project Manager, at 301-796-5295.

4 COMMENTS TO THE APPLICANT

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

¹ Schlick, James. Proprietary Name Review for Xuriden (IND (b) (4)). 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); 2012 April 13. OSE RCM No.: 2011-4185.

² Barlow, Matthew. Proprietary Name Review for Xuriden (IND 118931). 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); 2014 July 29. OSE RCM No.: 2014-17316.

If any of the proposed product characteristics as stated in your 20 January 2015 Request for Proprietary Name Review are altered, the name must be resubmitted for review.

5 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. **Phonetic and Orthographic Computer Analysis (POCA)**

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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/s/

RHIANNON LEUTNER
02/18/2015

JO H WYETH
02/18/2015