

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**125509Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

**Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Surveillance and Epidemiology  
Office of Medication Error Prevention and Risk Management**

**Proprietary Name Memorandum**

Date: May 15, 2015

Reviewer: Jacqueline Sheppard, PharmD  
Division of Medication Error Prevention and Analysis

Team Leader: Vicky Borders-Hemphill, PharmD  
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Anthim (obiltoximab) Injection, 600 mg/6 mL (100 mg/mL)

Application Type/Number: BLA 125509

Applicant/Sponsor: Elusys Therapeutics

OSE RCM #: 2015-81086

\*\*\* This document contains proprietary and confidential information that should not be released to the public.\*\*\*

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## **1 INTRODUCTION**

This memorandum is to re-assess the proposed proprietary name, Anthim, under BLA 125509. DMEPA previously found the name Anthim acceptable for this product in OSE Review# 2014-26229 dated October 2, 2015. As the name was conditionally approved under IND 12285, the Applicant re-submitted the name Anthim for review on April 6, 2015 under the BLA. We do note detailed pediatric dosing recommendations were provided at BLA submission. All product characteristics remain the same.

## **2 METHODS AND DISCUSSION**

To reassess the proposed proprietary name, DMEPA searched the POCA database (see Section 4) and conducted a gap analysis to identify names approved since the previous OSE Proprietary Name Review #2014-26229 that have orthographic and phonetic similarities to the proposed name Anthim. Our POCA search did not identify any new names that represent a potential source of drug name confusion. One new name was further evaluated and can be found in Appendix A.

We re-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. Furthermore, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The May 11, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Lastly, we reviewed the product characteristics in the current proprietary name submission and compared them to the product characteristics in the previous proprietary name review. We determined that none of the product characteristics have changed since the last proprietary name review.

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Anti-Infective Products (DAIP) concurred with the findings of OPDP's assessment of the proposed name.

As a result, we maintain that the name, Anthim, is acceptable.

## **3 CONCLUSIONS**

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

If you have further questions or need clarifications, please contact Karen Townsend, OSE Project Manager, at 301-796-5413

### **3.1 COMMENTS TO THE APPLICANT/SPONSOR**

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

If any of the proposed product characteristics as stated in your April 6, 2015 re-submission are altered, the name must be resubmitted for review.

#### 4 REFERENCES

1. Neupauer D. Proprietary Name Review for Anthim (IND 12285). 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 Oct 2. OSE RCM No.: 2014-26229.
2. **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.
3. ***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.

## APPENDICES

**Appendix A:** Moderately Similar Names (i.e., combined POCA score is  $\geq 50\%$  to  $\leq 69\%$ ) with overlap or numerical similarity in Strength and/or Dose

<b>No.</b>	<b>Proposed name: Anthim Strength: 600 mg/6 ml Usual Dose: 16 mg/kg – 32 mg/kg once</b>	<b>POCA Score (%)</b>	<b>Orthographic and/or phonetic differences in the names sufficient to prevent confusion Or Failure prevention reasons Prevention of Failure Mode</b>
1.	Antibac	56	The suffixes of these name pair have sufficient orthographic differences.  The second and third syllables of these name pairs sound different. Additionally, Antibac has 3 syllables and Anthim has 2 syllables.

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/s/  
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05/15/2015

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05/15/2015