CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

125388Orig1s000

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

Date:	June 8, 2011
Reviewer(s):	Lissa C. Owens, PharmD, Safety Evaluator 6/8/11 Division of Medication Error Prevention and Analysis
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Division Director	Carol Holquist, RPh, Director 6/8/11 Division of Medication Error Prevention and Analysis
Drug Name and strength:	Adcetris (Brentuximab Vedotin) for Injection 50 mg/vial
Application Type/Number:	BLA 125388 BLA 125399
Applicant/sponsor:	Seattle Genetics
OSE RCM #:	2011-1052

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CONTENTS

1 INTRODUCTION

This review responds to a request from Seattle Genetics dated March 17, 2011 for a promotional and safety assessment of the proposed proprietary name, Adcetris. In addition, the anticipated approval of the two BLAs associated to the proposed name Adcetris, is within 90 days from the date of this review. DMEPA found the proposed proprietary name, Adcetris, acceptable under IND 071634 in OSE Review #2010-2030, dated March, 11 2011. DDMAC re-reviewed the proposed name on March 31, 2011 and again had no concerns regarding the proposed name from a promotional perspective.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review # 2010-2030. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded one new name ([(b) (4)]***), thought to look or sound similar to Adcetris and represent a potential source of drug name confusion.

Failure Mode and Effects Analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with Adcetris and lead to medication errors. This analysis determined that the name similarity between Adcetris and the identified name was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of June 2, 2011.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Adcetris, did not identify any vulnerabilities that would result in medication errors with the additional name noted in this review. Thus, DMEPA has no objection to the proprietary name, Adcetris, for this product at this time.

DMEPA considers this a final review; however, if approval of the BLA is delayed beyond 90 days from the date of this review, the Division of Biologic Oncology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If the Division has further questions or need clarifications, please contact Sue Kang, OSE project manager, at 301-796-4216.

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4 REFERENCES

1. **OSE Review 2010-2030; Adcetris Proprietary Name Review, March 11, 2011, Fava, W.**

2. ***Drugs@FDA*** *(http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)*

   Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

3. ***USAN Stems*** *(http://www.ama-assn.org/resources/doc/usan/stem-list-cumulative.pdf)*

   USAN Stems List contains all the recognized USAN stems.

4. ***Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request***

   Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

Appendix A: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

Proposed name: **Adcetris** **(Brentuximab Vedotin)**	**Strength:** **50 mg/vial** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Usual dose:** 1.8 mg/kg which is withdrawn from the vials and added to an intravenous infusion bag of 0.9% Sodium Chloride Injection to a final concentration of 0.4 mg to 1.2 mg/mL and is then administered as an intravenous infusion over 30 minutes once every three weeks.
Failure Mode: Name confusion	**Causes (could be multiple)**	**Prevention of failure mode leading to medication error**
[redacted]		

(b) (4)

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