CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761041Orig1s000

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)

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Date of This Memorandum:	March 4, 2016
OND Review Office or Division:	Division of Oncology Products 1 (DOP1)
Application Type and Number:	BLA 761034 and BLA 761041
Product Name and Strength:	Tecentriq (atezolizumab) Injection, 60 mg/mL
Total Product Strength	1,200 mg/20 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Submission Date:	December 18, 2015 (BLA 761034) and February 19, 2016 (BLA 761041)
Applicant/Sponsor Name:	Genentech, Inc.
Panorama #:	2015-2312188 and 2016-6904876
DMEPA Primary Reviewer:	Otto L. Townsend, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

The proposed proprietary name, Tecentriq, was reviewed by DMEPA on June 17, 2015 under IND 120827 and IND 117296 and found conditionally acceptable.[1] We note that the product characteristics remain the same in both current submissions.

[1] Mathew, D. Proprietary Name Review for Tecentriq (IND 120827 and IND 117296). 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); 2015 JUN 17. OSE RCM No.: 2015-79245 and 2015-453681.

2 METHODS AND DISCUSSION

To reassess the proposed proprietary name, we searched the POCA database[2,3] to identify names with orthographic and phonetic similarities that were not identified in the previous OSE proprietary name review. Our POCA search yielded six names with POCA scores of 50% or above that were not identified in our previous review. We determined that none of the names would pose a risk for confusion as described in the table below.

[2] **Phonetic and Orthographic Computer Analysis (POCA)**: 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.

[3] **POCA Search Criteria:** Date searched: January 22, 2016; Databases searched: Drugs@FDA and Names Entered by Safety Evaluators

No.	**Proposed name:** Tecentriq **Established name:** atezolizumab **Dosage form:** Injection **Strength(s):** 1,200 mg/20 mL (60 mg/mL) **Usual Dose:** 1,200 mg administered by intravenous infusion every three weeks	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	(b) (4) ***	54	Proposed Proprietary Name found unacceptable by DMEPA (OSE# (b) (4)). The Sponsor has not submitted an alternative Proposed Proprietary Name for review.
2.	(b) (4) ***	60	No overlap or numerical similarity in Strength and/or Dose.
3.	(b) (4) ***	60	The infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
4.	(b) (4) ***	51	Proposed Proprietary Name found unacceptable by DMEPA (OSE# (b) (4)). The Sponsor has withdrawn the name and submitted an alternative Proposed Proprietary Name for review.
5.	Trintellix ***	50	No overlap or numerical similarity in Strength and/or Dose.
6.	(b) (4) ***	52	No overlap or numerical similarity in Strength and/or Dose.

[4]The USAN stem list is available at the web page: http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page

Additionally, we searched the USAN stem list[4] to determine if the name contains any USAN stems as of the last USAN update.

Our re-assessment did not identify any new names that represent a potential source of drug name confusion. Our January 29, 2016 search of USAN stems did not yield any USAN stems that are present in the proposed proprietary name.

3 CONCLUSIONS

The proposed proprietary name, Tecentriq, is acceptable from both a misbranding and safety perspective under BLA 761034 and BLA 761041.

If you have further questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager at 301-796-0942.

4 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 18, 2015 (BLA 761034) or February 19, 2016 (BLA 761041) submissions are altered prior to approval of the marketing application, the name must be resubmitted for review.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

OTTO L TOWNSEND
03/04/2016

CHI-MING TU
03/04/2016