CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761143Orig1s000

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:	January 14, 2020
Application Type and Number:	BLA 761143
Product Name and Strength:	Tepezza (Fepezo) for injection, 500 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Horizon Pharma (Horizon)
Panorama #:	2020-37118750
DMEPA Primary Reviewer:	Nasim Roosta, PharmD
DMEPA Team Leader:	Otto L. Townsend, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Tepezza, which was previously found conditionally acceptable[a] then subsequently found unacceptable under IND 112952 on June 24, 2019.[b] The proposed proprietary name, Tepezza, was found to be vulnerable to medication errors due to confusion with another proposed proprietary name, (b) (4)***, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Tepezza, was dependent upon which underlying application was approved first.

The marketing application for Tepezza has since been submitted (BLA 761143), and we note that the intended action date for Tepezza's application has been pushed up by the Division of Transplant and Ophthalmology (DTOP), whereas the underlying application for (b) (4)*** has an action date of (b) (4). Therefore, if the proposed proprietary name, Tepezza, is granted approval under BLA 761143 on or before January 15, 2020, this application approval will precede approval of the application with the conflicting proposed name, (b) (4)***.

Thus, Horizon resubmitted the proposed proprietary name, Tepezza, for reconsideration.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

Prior to finding the proposed proprietary name, Tepezza unacceptable, we had found the proposed proprietary name conditionally acceptable.[a] Therefore, for re-assessment of the proposed proprietary name, we conducted a gap analysis and searched the Phonetic and Orthographic Computer Analysis (POCA) database to identify names with orthographic and phonetic similarity to the proposed name that have been approved since our previous proprietary name review where we had found the proposed proprietary name conditionally acceptable. We also 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. Our January 13, 2020 search of POCA identified four new names not previously identified: (b) (4)***, (b) (4)***, Katerzia, and (b) (4)***. These names do not represent a potential source of drug name confusion as described in Appendices C and E. Additionally, we searched the United States Adopted Names (USAN) approved stems list to determine if the name contains any USAN stems as of the last USAN updates. The January 13, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Based upon our safety assessment of the proposed proprietary name, Tepezza, the pushed-up application goal date for BLA 761143, and the status of the underlying application for (b) (4)***, we find the proposed proprietary name, Tepezza, conditionally acceptable.

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[a] Roosta, N. Proprietary Name Review for Tepezza (IND 112952). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 FEB 21. Panorama No. 2018-27985805.

[b] Fanari, M. Proprietary Name Review for Tepezza (IND 112952). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUN 24. Panorama No. 2018-27985805-1.

2.2 COMMUNICATION OF DMEPA'S ANALYSIS

DMEPA communicated our findings to the Division of Transplant and Ophthalmology Products (DTOP) via e-mail on January 14, 2020.

3 CONCLUSION

The proposed proprietary name, Tepezza, is acceptable.

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

3.1 COMMENTS TO HORIZON PHARMA

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

If any of the proposed product characteristics as stated in your submission, received on January 13, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

4 REFERENCES

1. 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.

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.

5 APPENDICES

Appendix A: – Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Tepezza **Established name:** (b) (4) **Dosage form:** for injection **Strength(s):** 500 mg **Usual Dose:** IV infusion of 10 mg/kg for the initial treatment followed by an IV infusion of 20 mg/kg every three weeks. The recommended course of therapy is eight infusions.	**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.**
	N/A		

Appendix B: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
	N/A	

Appendix C: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Tepezza **Established name:** (b) (4) **Dosage form:** for injection **Strength(s):** 500 mg **Usual Dose:** IV infusion of 10 mg/kg for the initial treatment followed by an IV infusion of 20 mg/kg every three weeks. The recommended course of therapy is eight infusions.	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	(b) (4)***	58	This name pair has sufficient orthographic and phonetic differences.
2.	Katerzia	58	This name pair has sufficient orthographic and phonetic differences.
3.	(b) (4)***	56	This name pair has sufficient orthographic and phonetic differences.

Appendix D: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
	N/A	

Appendix E: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
	(b) (4) ***	65	This is the alternate proposed proprietary name submitted under this NDA. Horizon requested withdrawal of this proposed proprietary name and they have requested review of the proposed proprietary name, Tepezza, which is the subject of this review.

Appendix F: Names not likely to be confused due to absence of attributes that are known to cause name confusion[c].

No.	Name	POCA Score (%)
1.	N/A	

[c] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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/s/

NASIM N ROOSTA
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MEMORANDUM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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 Review:	October 31, 2019
Responsible OND Division:	Division of Transplant and Ophthalmology Products (DTOP)
Application Type and Number:	BLA 761143
Product Name and Strength:	(b) (4) (teprotumumab-trbw) for injection, 500 mg/vial
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Horizon Pharma Ireland Limited (Horizon Pharma)
FDA Received Date:	July 8, 2019
OSE RCM #:	2019-1480
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

[a] Proposed proprietary name currently under review.

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffixes proposed by Horizon Pharma for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761143.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On July 8, 2019, Horizon Pharma submitted a list of 6 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Horizon Pharma also provided findings from an external study conducted (b) (4) evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Horizon Pharma:

Table 1. Suffixes submitted by Horizon Pharma***	
1.	trbw
2.	(b) (4)
3.	
4.	
5.	
6.	

We reviewed Horizon Pharma's proposed suffixes in order of preference listed by Horizon Pharma, along with the supporting data they submitted, using the principles described in the applicable guidance.[c]

2.1 teprotumumab-trbw

Horizon Pharma's first proposed suffix, -trbw, is composed of four distinct letters.

We determined that the proposed suffix -trbw, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. Per an email correspondence dated October 30, 2019, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Transplant and Ophthalmology Products (DTOP) via e-mail on October 31, 2019.

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[a] Request for Proposed Suffix Review. Dublin (Ireland): Horizon Pharma Ireland, Ltd.; 2019 Jul 07. Available from: \\cdsesub1\evsprod\bla761143\0001\m1\us\request-for-suffix-review.pdf

[b] Data Summary for Proposed Suffixes. Miami (FL) (b) (4) 2019 May 28. Available from: \\cdsesub1\evsprod\bla761143\0001\m1\us\request-for-suffix-review.pdf

[c] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

4 CONCLUSION

We find Horizon Pharma's proposed suffix -trbw acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to teprotumumab-trbw. DMEPA will communicate our findings to the Applicant via letter.

4.1 Recommendations for Horizon Pharma Ireland Limited

We find the nonproprietary name, teprotumumab-trbw, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, teprotumumab-trbw will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we would inform you of our finding.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CARLOS M MENA-GRILLASCA
10/31/2019 05:53:38 PM

DANIELLE M HARRIS
11/01/2019 01:47:51 PM