

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761071Orig1s000

PROPRIETARY NAME REVIEW(S)

MEMORANDUM
NONPROPRIETARY NAME SUFFIX

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:	September 14, 2018
Responsible OND Division:	Division of Pulmonary, Allergy, and Rheumatology Products (DPARP)
Application Type and Number:	BLA 761071
Product Name and Strength:	Hyrimoz (adalimumab-adaz) Injection, 40 mg/0.8 mL
Product Type:	Single Ingredient Combination Product (Biological-Device)
Applicant/Sponsor Name:	Sandoz Inc.
FDA Received Date:	February 26, 2018
OSE RCM #:	2018-435
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffixes proposed by Sandoz for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761071.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On February 26, 2018, Sandoz submitted a list of five suffixes, in their order of preference, to be used in the nonproprietary name of their product^a. Sandoz also provided findings from an external study conducted by (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 Sandoz:

1.	(b) (4)
2.	(b) (4)
3.	(b) (4)
4.	(b) (4)
5.	adaz

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

2.1 adalimumab- (b) (4)



^a Cover Letter- Request for Review of Preferred Nonproprietary Name Four Letter Suffixes. Princeton (NJ): Sandoz Inc.; 2018 FEB 26. Available from: <\\cdsesub1\evsprod\bla761071\0017\m1\us\12-cover-letters\cover-letter.pdf>

^b Data Summary for Proposed Suffixes. (b) (4) 2018 FEB 22. Available from: Available from: <\\cdsesub1\evsprod\bla761071\0017\m1\us\111-information-amendment\sandoz-ada-suffix-fda-report.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>

2.2 adalimumab- (b) (4)



(b) (4)

2.3 adalimumab- (b) (4)



(b) (4)

2.4 adalimumab-^{(b) (4)}

(b) (4)

2.5 adalimumab-adaz

Sandoz's fifth proposed suffix, -adaz, is comprised of three distinct letters ('a', 'd', and 'z'). Although the letters 'ada' are common to the core name **adalimumab**, we could not identify a plausible risk related to the suffix evoking the core name adalimumab.

We note that some of the letters in the suffix represent medical abbreviations ('ada' is an abbreviation for 'azadicarbonamide'; 'daz' is an abbreviation for 'diazepam', 'diazoxide', etc.; 'ad' is an abbreviation for 'right ear' and 'adrenostenedione'; 'da' is an abbreviation for 'dopamine'; 'az' is an abbreviation for 'azathioprine'). We considered whether the inclusion of the letters ('ada', 'daz', 'da', 'az') within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or, based upon known causes of medication errors.

The proposed suffix -adaz is similar to the drug product Apadaz (acetaminophen and benzhydrocodone hydrochloride). However, Apadaz is a schedule II controlled substance (CII) with multiple product characteristics differences with adalimumab (i.e. different dosage forms, route of administration, and dosing). Furthermore, the additional letters 'Ap' at the beginning of the name Apadaz help differentiate the name from the suffix -adaz. Therefore, we could not identify a plausible risk based on the expected use of these products or, based upon known causes of medication errors.

We determined that the proposed suffix -adaz, 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, TBBS, and ORP. In email correspondence dated September 7, 2018, the workgroup concurred with DMEPA's assessment and conclusion. DMEPA also communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on September 14, 2018.

4 CONCLUSION

We find Sandoz's proposed suffix -adaz acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to adalimumab-adaz.

4.1 Recommendations for Sandoz

We find the nonproprietary name, adalimumab-adaz, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, adalimumab-adaz will be the proper name designated in the license and you should revise your proposed labels and labeling accordingly. 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.

We also note that your first four proposed suffix candidates are unacceptable for the following reasons:

1.



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/s/

CARLOS M MENA-GRILLASCA
09/14/2018

DANIELLE M HARRIS
09/18/2018

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 Review:	January 4, 2018
Application Type and Number:	BLA 761071
Product Name and Strength:	Hyrimoz and Hyrimoz Sensoready Pen (GP2017)* 40 mg/0.8 mL
Product Type:	Single-ingredient, drug-device combination product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sandoz
Panorama #:	2017- 18755325 and 2017- 18815370
DMEPA Primary Reviewer:	Teresa McMillan, PharmD
DMEPA Team Leader:	Sarah K. Vee, PharmD

* Hyrimoz and Hyrimoz Sensoready Pen have been developed as a proposed biosimilar to US-licensed Humira (adalimumab). Since the proper names for Hyrimoz and Hyrimoz Sensoready Pen have not yet been determined, GP2017 is used throughout this review as the nonproprietary name for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary names, Hyrimoz and Hyrimoz Sensoready Pen, which was found conditionally acceptable under IND 115732 on June 16, 2017.^a We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Division of Pulmonary, Allergy and Rheumatology Products (DPARP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

Our POCA search identified 24 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. We had identified and evaluated 33 names in our previous proprietary name review.^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 name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. We did not identify any names not previously analyzed.

Additionally, DMEPA also searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The December 20, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary names.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Division of Pulmonary, Allergy and Rheumatology Products (DPARP) via e-mail on December 21, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DPARP on January 3, 2018, they stated no additional concerns with the proposed proprietary names, Hyrimoz and Hyrimoz Sensoready Pen.

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Saharat Patanavanich, OSE project manager, at 240-402-0139.

^a McMillan, T. Proprietary Name Review for IND 115732. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 JUN 16. Panorama No. 2015-2318722 and 2015-2318977.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary names, Hyrimoz and Hyrimoz Sensoready Pen, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your October 30, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 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.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm

(<http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#>).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

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/s/

TERESA S MCMILLAN
01/04/2018

SARAH K VEE
01/04/2018