CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206088Orig1s000

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:	April 22, 2014
Requesting Office or Division:	Division of Dermatology and Dental Products (DDDP)
Application Type and Number:	NDA 206088
Product Name and Strength:	Otezla (apremilast) Tablets, 10 mg, 20 mg, 30 mg
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Celgene Corporation
Submission Date:	02/21/2014
Panorama #:	2014-16976
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, RPh
DMEPA Associate Director:	Lubna Merchant, MS, PharmD

1 INTRODUCTION

The proposed proprietary name Otezla was found acceptable for NDA 205437, approved on March 21, 2014 for the indication of active psoriatic arthritis. We note that the tablet strengths, dose titration, and maintenance dose for the psoriasis indication currently under review in NDA 206088 are the same as for the psoriatic arthritis indication. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Otezla, is acceptable from both a promotional and safety perspective for NDA 206088.

If you have further questions or need clarifications, please contact Teena Thomas, OSE project manager, at 301-796-0549.

1.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your February 21, 2014 submission are altered, the name must be resubmitted for review.

REFERENCES

1. OSE Review #2013-789, Proprietary Name Review for Otezla (Apremilast) NDA 205437, June 20, 2013, McMillan, T.

2. OSE Review #2013-789-1, Proprietary Name Memo for Otezla (Apremilast) NDA 205437, January 29, 2014, McMillan, T.

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/s/

CARLOS M MENA-GRILLASCA
04/22/2014

LUBNA A MERCHANT
04/22/2014

LABEL AND LABELING REVIEW

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:	April 10, 2014
Requesting Office or Division:	Division of Dermatology and Dental Products (DDDP)
Application Type and Number:	NDA 206088
Product Name and Strength:	Otezla (apremilast) Tablets, 10 mg, 20 mg, 30 mg
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Celgene Corporation
Submission Date:	April 1, 2014
OSE RCM #:	2014-423
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, RPh
DMEPA Associate Director:	Lubna Merchant, MS, PharmD

1 REASON FOR REVIEW

This review responds to a request from DDDP to evaluate the proposed container labels and carton labeling for Otezla (NDA 206088) for areas of vulnerability that could lead to medication errors. Otezla was approved on March 21, 2014 under NDA 205437 for the indication of active psoriatic arthritis.

2 MATERIALS REVIEWED

We considered the materials listed in Table 1 for this review. The Appendices provide the methods and results for each material reviewed.

Table 1. Materials Considered for this Label and Labeling Review

Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
FDA Adverse Event Reporting System (FAERS)	n/a
Previous DMEPA Reviews	B
Human Factors Study	n/a
ISMP Newsletters	n/a
Other	n/a
Labels and Labeling	C

N/A=not applicable for this review

3 OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

The applicant is proposing to market Otezla in the same packaging presentations already approved for NDA 205437 in March 21, 2014 for the psoriatic arthritis indication. We note that the tablet strengths, dose titration, and maintenance dose for the psoriasis indication currently under review in NDA 206088 are the same as for the psoriatic arthritis indication. We compared the proposed labels and labeling and note that the applicant submitted the same labels and labeling recently reviewed by DMEPA for NDA 205437 and found acceptable. Therefore, we do not have any additional recommendations for the proposed labels and labeling.

However, we note that the storage conditions in the currently marketed labels and labeling only indicate an upper temperature limit (i.e. Store tablets below 30 °C (86°F)). Customarily storage conditions provide a range of upper and lower temperature limits, with excursions permitted. This was discussed during the labeling meeting and DMEPA deferred to CMC for their recommendation.

4 CONCLUSIONS

DMEPA finds the proposed labels and labeling acceptable.

APPENDICES: METHODS & RESULTS FOR EACH MATERIALS REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 2 presents relevant product information for Otezla that Celgene Corporation submitted on January 30, 2014.

Table 2. Relevant Product Information for Otezla	
Active Ingredient	Apremilast
Indication	Approved: active psoriatic arthritis Proposed: moderate to severe psoriasis
Route of Administration	Oral
Dosage Form	Tablets
Strength	10 mg, 20 mg, 30 mg
Dose and Frequency	To reduce risk of gastrointestinal symptoms, titrate to recommended dose of 30 mg twice daily according to the following schedule: Day 1: 10 mg in morning Day 2: 10 mg in morning and 10 mg in evening Day 3: 10 mg in morning and 20 mg in evening Day 4: 20 mg in morning and 20 mg in evening Day 5: 20 mg in morning and 30 mg in evening Day 6 and thereafter: 30 mg twice daily
How Supplied	2-week starter pack 30 mg tablets in 60 count bottles 28 count carton (2 blister cards of 14- 30 mg tabs)
Storage	Store tablets below 30 °C (86°F).

APPENDIX B. PREVIOUS DMEPA REVIEWS

B.1 Methods

We searched the L: drive on April 10, 2014 using the term Onexton to identify reviews previously performed by DMEPA.

B.2 Results

DMEPA reviewed Otezla labels and labeling during the review cycle of NDA 205437 in the following OSE reviews:

- 2013-790, dated September 12, 2013
- 2013-790-1, dated December 18, 2013
- 2013-790-2, dated March 5, 2013

We note that all of DMEPA's recommendations were implemented prior to approval of NDA 205437 on March 21, 2014.

APPENDIX D. LABELS AND LABELING

C.1 List of Labels and Labeling Reviewed

In addition, we reviewed the currently marketed labels and labeling for Otezla approved on March 21, 2014 for NDA 205437 to ensure that they are the same as the proposed labels for NDA 206088 currently under review.

- Container label
- Carton labeling

C.2 Label and Labeling Images (not to scale)

(b) (4)

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/s/

CARLOS M MENA-GRILLASCA
04/10/2014

LUBNA A MERCHANT
04/11/2014