APPLICATION NUMBER:

761055Orig1s000

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***

<table>
<thead>
<tr>
<th>Date of This Review:</th>
<th>August 25, 2016</th>
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<tr>
<td>Application Type and Number:</td>
<td>BLA 761055</td>
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<tr>
<td>Product Name and Strength:</td>
<td>Dupixent (dupilumab) Injection 300 mg Prefilled Syringe</td>
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<td>Product Type:</td>
<td>Single Ingredient Combination Product</td>
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<td>Rx or OTC:</td>
<td>Rx</td>
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<td>Applicant/Sponsor Name:</td>
<td>Regeneron Pharmaceuticals, Inc.</td>
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<td>Panorama #:</td>
<td>2016-9450650</td>
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<tr>
<td>DMEPA Primary Reviewer:</td>
<td>Carlos M Mena-Grillasca, RPh</td>
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<td>DMEPA Team Leader:</td>
<td>Mishale Mistry, PharmD, MPH</td>
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Reference ID: 3977555
1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Dupixent, which was found conditionally acceptable under IND 107969 and IND on April 29, 2016. 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 Dermatology and Dental Products (DDDP) concurred with the findings of OPDP’s assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA 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. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The August 25, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

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 from a promotional and safety perspective.

If you have any questions or need clarifications, please contact Tri Minh Bui-Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your August 2, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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Reference ID: 3977555
4 REFERENCES


USAN Stems List contains all the recognized USAN stems.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

Carlos M Mena-Grillasca
08/25/2016

Mishale P Mistry
08/26/2016

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