CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208772Orig1s000

 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>September 6, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Type and Number:</td>
<td>NDA 208772</td>
</tr>
<tr>
<td>Product Name and Strength:</td>
<td>Alunbrig (brigatinib) Tablets, 30 mg and 90 mg</td>
</tr>
<tr>
<td>Product Type:</td>
<td>Single Ingredient Product</td>
</tr>
<tr>
<td>Rx or OTC:</td>
<td>Rx</td>
</tr>
<tr>
<td>Applicant/Sponsor Name:</td>
<td>Ariad Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td>Panorama #:</td>
<td>2016-9945598</td>
</tr>
<tr>
<td>DMEPA Primary Reviewer:</td>
<td>Janine Stewart, PharmD</td>
</tr>
<tr>
<td>DMEPA Team Leader:</td>
<td>Chi-Ming (Alice) Tu, PharmD</td>
</tr>
</tbody>
</table>

Reference ID: 3982308
1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Alunbrig, which was found conditionally acceptable under IND 110935 on November 10, 2015.\textsuperscript{a}

We note, compared to IND 110935, there are changes in the proposed indication and in the proposed packaging configurations listed in the “How Supplied” section of the Prescribing Information (PI) for NDA 208772. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 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. We also evaluated previously identified names taking into account the proposed change in indication and in the proposed packaging configurations listed in the “How Supplied” section of the PI (see Table 1). Our evaluation has not 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 September 1, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Table 1. Comparison of proposed indication and packaging configurations between NDA and IND

<table>
<thead>
<tr>
<th>Alunbrig (brigatinib) Tablets</th>
<th>NDA 208772</th>
<th>IND 110935</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication Of Use:</td>
<td>For the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.</td>
<td></td>
</tr>
</tbody>
</table>

\textsuperscript{a} Townsend, Otto. Proprietary Name Review for Alunbrig (IND 110935). 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 NOV 10. Panorama No. 2015-1333175.
### 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 promotional and safety perspective.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

#### 3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your June 16, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.
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.

/s/

JANINE A STEWART
09/06/2016

CHI-MING TU
09/06/2016