

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**761070Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**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\*\*\***

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<b>Date of This Review:</b>	July 26, 2017
<b>Application Type and Number:</b>	BLA 761070
<b>Product Name and Strength:</b>	Fasenra (benralizumab) Injection 30 mg/mL
<b>Product Type:</b>	Single ingredient, combination product
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	AstraZeneca
<b>Panorama #:</b>	2017-15101216
<b>DMEPA Primary Reviewer:</b>	Teresa McMillan, PharmD
<b>DMEPA Team Leader:</b>	Sarah K. Vee, PharmD

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## 1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Fasenra, which was found unacceptable under IND 100237 on December 19, 2017.<sup>a</sup> The proposed proprietary name, Fasenra, was found to be vulnerable to medication errors due to confusion with two other products, (b) (4)\*\*\*, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Fasenra, was dependent upon which underlying application was approved first.

We note that the goal date for BLA 761070 is November 16, 2017, whereas the underlying application for, (b) (4)\*\*\* remains in IND status and the name (b) (4)\*\*\* was found unacceptable under NDA 208751.<sup>b</sup> Thus the Applicant for NDA 208751 submitted the proprietary name Fiasp\*\*\* on January 12, 2017. Fiasp\*\*\* was found conditionally acceptable on May 23, 2017.<sup>c</sup>

Thus, the applicant resubmitted the proposed proprietary name, Fasenra, for review.

## 2 DISCUSSION

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 July 5, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, DMEPA evaluated the status of the underlying applications of the conflicting names, (b) (4)\*\*\*. We determined the underlying application for (b) (4)\*\*\* remains in IND status. The proprietary name (b) (4)\*\*\* was found unacceptable in OSE Review #2016-8522346-1. Thus, Fiasp\*\*\* was submitted for NDA 208751 and found acceptable. Therefore, if the proposed proprietary name, Fasenra, is granted approval under BLA 761070 on or before the November 16, 2017 PDUFA goal date for the application, this application approval will precede approval of the application with the conflicting proposed name, (b) (4)\*\*\*. Additionally, because the proprietary name Fiasp\*\*\* was found conditionally acceptable for NDA 208751, the concern for name confusion with (b) (4)\*\*\* no longer exists.

Based upon our safety assessment of the proposed proprietary name, Fasenra, the application goal date for BLA 761061, the status of the underlying application for (b) (4)\*\*\*, and the

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<sup>a</sup>McMillan T. Proprietary Name Review for Fasenra (IND 100237). 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); 2016 DEC 19. RCM #. 2016-8932137.

<sup>b</sup>Conrad A. Proprietary Name Review for (b) (4)\*\*\* (NDA 208751). 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); 2016 DEC 15. RCM #. 2016-8522346-1

<sup>c</sup>Conrad A. Proprietary Name Review for Fiasp and Fiasp Flextouch (NDA 208751). 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); 2017 MAY 23. RCM #. 2017-14050537 and 2017-14162760.

replacement of the proposed proprietary name (b)(4)\*\*\* due the acceptability of the proposed proprietary name Fiasp\*\*\*, we find Fasenra conditionally acceptable.

### **2.1 COMMUNICATION OF DMEPA'S ANALYSIS**

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPAAP) via e-mail on July 14, 2017.

### **3 CONCLUSIONS**

We conclude that the proposed proprietary name, Fasenra, is acceptable.

If you have any questions or need clarifications, please contact Michael Sinks, OSE project manager, at 240-402-2684.

#### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your May 18, 2017 submission 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.

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/s/  
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TERESA S MCMILLAN  
07/26/2017

SARAH K VEE  
07/27/2017

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**PROPRIETARY NAME 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:** May 2, 2017  
**Application Type and Number:** BLA 761070  
**Product Name and Strength:** (b) (4)  
(Benralizumab)  
Injection  
30 mg/mL  
**Product Type:** Single ingredient drug-device combination Product  
**Rx or OTC:** Rx  
**Applicant/Sponsor Name:** AstraZeneca  
**Panorama #:** 2017-13059521  
**DMEPA Primary Reviewer:** Teresa McMillan, PharmD  
**DMEPA Team Leader (Acting):** Sarah K. Vee, PharmD  
**DMEPA Associate Director:** Mishale Mistry, PharmD, MPH  
**DMEPA Division Director:** Todd Bridges, RPh

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/s/  
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TERESA S MCMILLAN  
05/02/2017

SARAH K VEE  
05/02/2017

MISHALE P MISTRY  
05/02/2017

DANIELLE M HARRIS on behalf of TODD D BRIDGES  
05/03/2017