

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**200671Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**PROPRIETARY NAME REVIEW 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>	November 06, 2014
<b>Application Type and Number:</b>	NDA 200671
<b>Product Name and Strength:</b>	Durlaza (acetylsalicylic acid) Capsules 162.5 mg
<b>Product Type:</b>	Single Ingredient Product
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	New Haven Pharmaceuticals Inc.
<b>Submission Date:</b>	September 25, 2014
<b>Panorama #:</b>	2014-36962
<b>DMEPA Primary Reviewer:</b>	Janine Stewart, PharmD
<b>DMEPA Team Leader:</b>	Chi-Ming (Alice) Tu, PharmD

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## **1 INTRODUCTION**

The proposed proprietary name, Durlaza, was found acceptable in OSE Review # 2014-17329, dated August 13, 2014 under IND 116348.<sup>1</sup> We note that product characteristics are the same for NDA 200671 currently under review as the IND. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Durlaza, is acceptable from both a promotional and safety perspective under the NDA 200671.

### **1.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your September 25, 2014 submission are altered, the name must be resubmitted for review. If you have further questions or need clarifications, please contact Cheryle Milburn, OSE project manager, at 301-796-2084.

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<sup>1</sup> Olumba J. Proprietary Name Review for Durlaza (IND 116348). 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); 20140813. 25 p. OSE RCM No.: 2014-17329.

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/s/  
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JANINE A STEWART  
11/06/2014

CHI-MING TU  
11/06/2014