

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**208462Orig1s000**

**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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**Date of This Review:** August 25, 2015  
**Requesting Office or Division:** Division of Hematology Products (DHP)  
**Application Type and Number:** NDA 208462  
**Product Name and Strength:** Ninlaro (Ixazomib) Capsules,  
2.3 mg, 3 mg, 4 mg  
**Product Type:** Single Ingredient  
**Rx or OTC:** Rx  
**Applicant/Sponsor Name:** Millennium Pharmaceuticals, Inc  
**Submission Date:** July 15, 2015  
**Panorama #:** 2015-969486  
**DMEPA Primary Reviewer:** Ebony Ayres, PharmD  
**DMEPA Team Leader:** Yelena Maslov, PharmD

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## 1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Ninlaro under NDA 208462, which was found conditionally acceptable under IND 104482 dated November 26, 2014<sup>1</sup>. We note that the minor product characteristic changes in indication, dosing, and storage requirements do not change our evaluation of the proposed proprietary name as they add details regarding product use, but essentially remain the same. Table 1 below summarizes the changes.

**Table 1. Product characteristics**

	<b>IND 104482</b>	<b>NDA 208462</b>
<b>Indication</b>	Treatment of [REDACTED] (b) (4) multiple myeloma	Treatment of patients with multiple myeloma who have received at least one prior therapy
<b>Dosing</b>	<ul style="list-style-type: none"><li>- The maximum daily dose varies depending on the dose strength (4 mg, 3 mg, 2.3 mg) prescribed. The frequency of administration is once weekly for three weeks in a four week cycle.</li></ul>	<ul style="list-style-type: none"><li>- 4 mg once a week on days 1, 8, and 15 of a 28-day treatment cycle. The maximum weekly dose may vary, but should not exceed 4 mg.</li><li>- Includes dosing for hepatic and renal impairment</li></ul>
<b>Storage</b>	This product should be stored at room temperature.	Do not store above 30°C (86°F). Do not freeze. May be stored at room temperature.

## 2. METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, we conducted a gap analysis and searched the POCA database to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review #2014-25813. Our POCA search did not identify any new names that represent a potential source of drug name confusion. Additionally, we searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The July 23, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

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<sup>1</sup> Rutledge, Michelle. Proprietary Name Review for Ninlaro (IND 104482). 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); 2014 Nov 26. OSE RCM No.: 2014-25813.

### **3. CONCLUSIONS**

DMEPA maintains the proposed proprietary name, Ninlaro, is acceptable from both a misbranding and safety perspective under NDA 208462.

If you have further questions or need clarifications, please contact Kevin Wright, OSE Project Manager, at (301) 796-3621.

### **4. COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your July 15, 2015 submission are altered, the name must be resubmitted for review.

## 5 REFERENCES

1. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)

USAN Stems List contains all the recognized USAN stems.

2. **Phonetic and Orthographic Computer Analysis (POCA)**

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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EBONY J AYRES  
08/25/2015

YELENA L MASLOV  
08/25/2015