

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**208524Orig1s000**

**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)

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<b>Date of This Review:</b>	November 3, 2015
<b>Application Type and Number:</b>	NDA 208524
<b>Product Name and Strength:</b>	Belviq XR (lorcaserin HCl) extended release tablets, 20 mg
<b>Product Type:</b>	Single ingredient
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Arena Pharmaceuticals, Inc.
<b>Submission Date:</b>	September 18, 2015
<b>Panorama #:</b>	2015-1524259
<b>DMEPA Primary Reviewer:</b>	Mishale Mistry, PharmD, MPH
<b>DMEPA Team Leader:</b>	Yelena Maslov, PharmD

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## 1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Belviq XR (NDA 208524). DMEPA previously found the name acceptable in OSE Review #2014-45073<sup>1</sup>, dated March 4, 2015.

### 1.1 PRODUCT INFORMATION

The following product information is provided in the September 18, 2015 proprietary name submission.

- Intended Pronunciation: bel' veek XR
- Active Ingredient: lorcaserin hydrochloride extended release
- Indication of Use:
  - An adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:
    - 30 kg/m<sup>2</sup> or greater (obese) or
    - 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbid condition, (e.g., hypertension, dyslipidemia, type 2 diabetes)
  - Limitations of Use:
    - The safety and efficacy of coadministration of BELVIQ XR with other products intended for weight loss including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations have not been established.
    - The effect of BELVIQ XR on cardiovascular morbidity and mortality has not been established.
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 20 mg
- Dose and Frequency:
  - The recommended dose is 20 mg administered orally once daily. The tablet must be swallowed whole and must not be chewed, crushed, or divided.
  - Do not exceed recommended dose.
  - Belviq XR can be taken with or without food.
  - Response to therapy should be evaluated by week 12. If a patient has not lost at least 5% of baseline body weight, discontinue Belviq XR, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

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<sup>1</sup> Mistry M. Proprietary Name Review for Belviq XR (IND 119664). 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 Mar 4. 11 p. OSE RCM No.: 2014-45073.

- How Supplied: Supplied as orange-colored, round, biconvex, film-coated tablets debossed with “A” on one side and “20” on the other side and are available in 30-count bottles.
- Storage: Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F) [see USP controlled room temperature].

## **2 METHODS AND DISCUSSION**

To reassess the proposed proprietary name, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The September 28, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Additionally, we conducted an updated FAERS search for name confusion errors involving Belviq that would be relevant for this review since the time of our last review<sup>1</sup>. The search yielded no relevant cases (See Appendix A for methodology of FAERS search).

Because we recently reviewed the name Belviq XR and there are no changes in product characteristics since the previous review, we maintain that the name is acceptable.

## **3 CONCLUSIONS**

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

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

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

#### 4 REFERENCES

1. Mistry M. Proprietary Name Review for Belviq XR (IND 119664). 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 Mar 4. 11 p. OSE RCM No.: 2014-45073.
2. *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.

## APPENDIX A

### *Medication Error Data Selection of Cases*

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 1 (see Appendix A1 for a description of FAERS database) for name confusion errors involving Belviq that would be relevant for this review.

<b>Table 1. FAERS Search Strategy</b>	
<b>Search Date</b>	September 28, 2015
<b>Drug Name</b>	Belviq [product name] Lorcaserin HCl [product active ingredient]
<b>Event (MedDRA Terms)</b>	<b>DMEPA Official Proprietary Name Review Search Terms Event List:</b> Product name confusion (PT) Medication error (PT) Intercepted medication error (PT) Drug dispensing error (PT) Intercepted drug dispensing error (PT) Circumstance or information capable of leading to a medication error (PT)
<b>Date Limits</b>	December 1, 2014 – September 28, 2015 (FDA Rcvd Dates)

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

The search yielded no relevant cases.

## **Appendix A1: Description of FAERS**

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>.

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/s/  
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11/03/2015

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