

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

208524Orig1s000

Trade Name: Belviq XR tablets,
20 mg

Generic Name: Lorcaserin Hydrochloride

Sponsor: Arena Pharmaceuticals, Inc.

Approval Date: July 15, 2016

Indication: This new drug application provides for the use of Belviq XR (lorcaserin hydrochloride) extended-release tablets, 20 mg, as 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 kg/m² or greater (obese) or 27 kg/m² (overweight) in the presence of at least one weight-related comorbid condition, (e.g. hypertension, dyslipidemia, type 2 diabetes).

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CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Other Action Letters	
Labeling	X
REMS	
Summary Review	X
Officer/Employee List	X
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	X
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology Review(s)	X
Statistical Review(s)	
Microbiology / Virology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	X
Other Reviews	X
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	X
Administrative/Correspondence Document(s)	X

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APPROVAL LETTER



NDA 208524

NDA APPROVAL

Arena Pharmaceuticals, Inc.
Attn: Craig M. Audet, Ph.D.
Sr. Vice President, Operations & Head of Global Regulatory Affairs
6154 Nancy Ridge Drive
San Diego, CA 92121

Dear Dr. Audet:

Please refer to your New Drug Application (NDA) dated and received September 18, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Belviq XR (lorcaserin hydrochloride) extended-release tablets, 20 mg.

This new drug application provides for the use of Belviq XR (lorcaserin hydrochloride) extended-release tablets, 20 mg, as 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/m² or greater (obese) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition, (e.g., hypertension, dyslipidemia, type 2 diabetes).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert and text for the patient package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed container labels that are identical to the enclosed container labels submitted on July 14 and 15, 2016, as soon as they are available, but no more than 30 days after they are

printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*.

Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 208524.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 6 years (inclusive) because the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group and is not likely to be used in a substantial number of pediatric patients in this group. Weight maintenance, not weight loss is the clinical goal for obese children 2 to 6 years of age. Weight loss is not recommended in children less than 2 years of age because of the requirement for adequate growth and development and optimal deposition of lipids in the developing nervous system.

We are deferring submission of your pediatric studies for ages 7 to 17 years (inclusive) for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(C) of the FDCA. These required studies are listed below.

Your requirements under PREA for PMRs 1900-3 and 1900-4, as stated in the approval letter for NDA 022529 for Belviq (lorcaserin hydrochloride) tablets, 10 mg, dated June 27, 2012, also apply to NDA 208524 for Belviq XR (lorcaserin hydrochloride) extended release tablets, 20 mg. Accordingly, your requirements under PREA are as follows:

- 1900-3 A 52-week, randomized, double-blind, placebo-controlled pediatric study to evaluate the safety and efficacy of Belviq for the treatment of obesity in pediatric patients ages 12 to 17 years (inclusive). You may not initiate this study until the results of your juvenile animal PMR study and the clinical

pharmacology (pediatric patients ages 12 to 17 years) PMR study have been submitted and reviewed by the Agency.

Final Protocol Submission: June 30, 2015
Study Completion: September 30, 2017
Final Report Submission: March 30, 2018

1900-4 A 52-week, randomized, double-blind, placebo-controlled pediatric study to evaluate the safety and efficacy of Belviq for the treatment of obesity in pediatric patients ages 7 to 11 years (inclusive). You may not initiate this study until results from the Belviq adolescent safety and efficacy PMR study (ages 12 to 17 years) and the clinical pharmacology PMR study (pediatric patients ages 7 to 11 years) have been submitted and reviewed by the Agency.

Final Protocol Submission: June 30, 2018
Study Completion: October 31, 2020
Final Report Submission: April 30, 2021

Submit the protocols to your IND 069888, with a cross-reference letter to NDA 022529 and to this NDA. We note that the protocol for PMR 1900-3 is currently under discussion with the Agency and refer to our comments issued on November 4, 2015, and to our Missed Milestone – Postmarketing Requirement letter issued on June 27, 2016.

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission “**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**” in large font, bolded type at the beginning of the cover letter of the submission.

Please cross-reference this NDA when you submit your final reports for requirements 1900-3 and 1900-4 to NDA 022529.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert, Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Patricia Madara, Regulatory Project Manager, at (301) 796-1249.

Sincerely,

{See appended electronic signature page}

James P. Smith, M.D., M.S.
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JAMES P SMITH
07/15/2016