

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### *APPLICATION NUMBER:*

**204592Orig1s000**

*Trade Name:* Zorvolex Capsules 18 mg and 35 mg.

*Generic Name:* diclofenac

*Sponsor:* Iroko Pharmaceuticals LLC.

*Approval Date:* October 18, 2013

*Indications:* For the treatment of mild to moderate acute pain in adults.

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## 204592Orig1s000

### CONTENTS

#### Reviews / Information Included in this NDA Review.

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

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*APPLICATION NUMBER:*

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**APPROVAL LETTER**



NDA 204592

**NDA APPROVAL**

Iroko Pharmaceuticals LLC  
One Kew Place  
15- Rouse Boulevard  
Philadelphia, PA 19112

Attention: Steve Jensen  
Sr. VP, Regulatory Affairs & Quality

Dear Mr. Jensen:

Please refer to your New Drug Application (NDA) dated and received December 20, 2012, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zorvolex (diclofenac) Capsules 18 mg and 35 mg.

We acknowledge receipt of your amendments dated January 30, February 4 and 12, March 6, April 8 and 30, August 15, 23, and 30, and October 1 and 10, 2013.

Reference is also made to your email dated Oct. 18, 2013, which included the final agreed-upon labeling.

This new drug application provides for the use of Zorvolex (diclofenac) Capsules 18 mg and 35 mg for the treatment of mild to moderate acute pain in adults.

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 agreed-upon labeling text.

**WAIVER OF HIGHLIGHTS SECTION**

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

**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 Medication Guide. 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 carton and immediate container labels that are identical to the enclosed carton and immediate container labels, 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 204592.**” 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.

### **MARKET PACKAGE**

Please submit one market package of the drug product when it is available to the following address:

Swati Patwardhan  
Food and Drug Administration  
Center for Drug Evaluation and Research  
White Oak Building 22, Room: 3170  
10903 New Hampshire Avenue  
Silver Spring, Maryland  
*Use zip code **20903** if shipping via United States Postal Service (USPS).*  
*Use zip code **20993** if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

### **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.

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