



NDA 22-348

**NDA APPROVAL**

Cumberland Pharmaceuticals  
2525 West End Avenue  
Suite 950  
Nashville, TN 37203

Attention: Amy D. Rock, Ph.D.  
Senior Manager, Regulatory Affairs

Dear Dr. Rock:

Please refer to your new drug application (NDA) dated December 3, 2008, received December 11, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Caldolor (Ibuprofen) Injection 400 mg/4 mL and 800 mg/8 mL.

We acknowledge receipt of your submissions dated December 30, 2008, and January 12, 19, and 28, February 4, 20, and 25, March 11 and 20, April 8, 15, 20, 22, 23, and 28, and May 12, 14, 15, 20, and 29, 2009.

This new drug application provides for the use of Caldolor (Ibuprofen) Injection 400 mg/4 mL and 800 mg/8 mL for reduction of fever, and the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics.

We have completed our review of this application, as amended and 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, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling text for the package insert. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 22-348.**"

### **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that are identical to the labels submitted on May 29, 2009, 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 titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. 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 22-348.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the products with labeling 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 indications in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies for ages 0 to 16 years until 2011 for the treatment of fever and until 2012 for the management of pain because this product is ready for approval for the use in adults and the pediatric studies have not been completed.

Your deferred pediatric study required under section 505B(a) of the FDCA is a required postmarketing study. The status of this post-marketing study must be reported annually according to 21 CFR 301.70 and section 505B(a)(3)(B) of the FDCA. These required studies are listed below.

1. Deferred pediatric study under PREA for the treatment of reduction in fever in pediatric patients ages 0 to 16 years.

Protocol Submission:	August 2009
Study Start Date:	October 2009
Final Report Submission:	January 2011

2. Deferred pediatric study under PREA for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics in pediatric patients ages 0 to 16 years.

Protocol Submission:	November 2010
Study Start Date:	January 2011
Final Report Submission:	January 2012

Submit final study reports to this NDA. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated “**Required Pediatric Assessment.**”

### **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



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Sharon Hertz

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