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PHARMACEUTICALS

20 August, 2014

Bob A. Rappaport, M.D.
Director, Division of Analgesics, Anesthetics, and Rheumatology Products
Office of Drug Evaluation II, Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, Maryland 20750-1266

RE: NDA 022348 CALDOLOR® (ibuprofen) Injection
RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED
IND 062605

Dear Dr. Rappaport,

Reference is made to NDA 022348 CALDOLOR® (ibuprofen) Injection submitted 11 December, 2008 and the 11 June, 2009 approval letter. Caldolor is indicated in adults for the management of mild to moderate pain, management of moderate to severe pain as an adjunct to opioid analgesics and for the reduction of fever. Reference is also made to the Notification of Non-Compliance with PREA dated 15 July, 2014 with a request to submit a response within 45 calendar days regarding the requirements of the Pediatric Research Equity Act. FDA also noted that a DEFERRAL EXTENSION REQUEST could be included with the submission.

The purpose of this submission is to respond to the Agency's Notification of Non-Compliance with PREA and the response can be found in Section 1.9.6. A Deferral Extension Request is also being submitted in Section 1.9.2. A cross-reference letter will be submitted to the IND and a copy of the cover letter will be sent to CDER Pediatric and Maternal Health Staff.

If you have any questions, please feel free to contact me by phone at (615) 255-0068, by fax (866) 438-2372 or by e-mail at bzaborny@cumberlandpharma.com.

Kind regards,

Beth A. Zaborny
Manager, Regulatory Affairs

cc: CDER Pediatric and Maternal Health Staff (cover letter)
IND 062605: Robert Justice, M.D; Attn: Swati Patwardhan, Regulatory Project Manager (cover letter)

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