DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 204623/S-006

APPROVAL LETTER

Horizon Pharma Inc.,
U.S. Agent for Horizon Pharma Ireland Limited
Attention: Jeffrey W. Sherman
Chief Medical Officer and Executive Vice President Research & Development
150 S. Saunders Road, Suite 400
Broomfield, CO 80038

Dear Dr. Sherman:

Please refer to your Supplemental New Drug Application (sNDA) dated February 16, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pennsaid® (diclofenac sodium topical solution) 2% w/w.

This "Changes Being Effected" supplemental new drug application provides for revision of the ethanol content based on absolute ethanol in the carton and container labels.

We have completed our review of this supplemental new drug application. This supplement is approved.

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 that 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).* Alternately, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weighted paper or similar material. For administrative purposes, designate this submission **"Final Printed Carton and Container Labels for approved NDA 204623/S-006**." 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.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Hongly La, Regulatory Business Process Manager, at 240-402-8681.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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