DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22511/S-015

SUPPLEMENT APPROVAL

Horizon Pharma, Inc.
Attention: Jeffrey W. Sherman, MD, FACP
CMO & Executive VP Research and Development
520 Lake Cook Road, Suite 520
Deerfield, IL 60015

Dear Dr. Sherman:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 29, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vimovo (naproxen/esomeprazole magnesium) Delayed-Release Tablets.

This "Prior Approval" supplemental new drug application provides for revisions to the commercial bottle and sample carton and bottle labels.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your March 18, 2015, amendment containing final printed carton and container labels.

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

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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE: Carton and Container Labeling

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/s/

JOYCE A KORVICK
03/25/2015