



NDA 021446/S-023, S-024
NDA 022488/S-001, S-002, S-003

**SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT**

C.P. Pharmaceuticals International C.V.
c/o Pfizer, Inc.
235 East 42nd Street
New York, NY 10017

Attention: Imran Shah
Associate Director
Worldwide Regulatory Strategy

Dear Mr. Shah:

Please refer to your following Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), for LYRICA[®] (pregabalin) Capsules, and for LYRICA[®] (pregabalin) Oral Solution.

Application Number	Supplement Number	Date Submitted	Date Received
NDA 021446	S-023	June 1, 2010	June 1, 2010
NDA 021446	S-024	September 3, 2010	September 3, 2010
NDA 022488	S-001	June 1, 2010	June 1, 2010
NDA 022488	S-002	September 3, 2010	September 3, 2010
NDA 022488	S-003	September 3, 2010	September 3, 2010

We acknowledge receipt of your amendments to NDA 022488/S-002 dated October 22 and 25, 2010, and your risk evaluation and mitigation strategy (REMS) assessments dated and received June 1, 2010, and September 3, 2010.

NDA 022488/S-002: This Prior Approval supplemental new drug application proposes the following changes: 1) a revised “**How Supplied/ Storage and Handling**” section of the US Package Insert (USPI) to remove the 45-day in-use period text, 2) a parallel proposed revision to the “**How Should I Store Lyrica**” section of the Medication Guide, and 3) artwork deleting the text “*Use within 45 days of first opening the bottle*” and “*Date bottle opened _____*” from the product container to align itself with the proposed changes to the USPI and medication guide.

NDA 021446/S-023, S-024 and NDA 22488/S-001, S-003: These Prior Approval supplemental new drug applications propose modification to the approved REMS to include revisions to the LYRICA[®] (pregabalin) Medication Guide.

We have completed our review of these supplemental applications, as amended. They are 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, 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, with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and 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 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 022488/S-002.” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REMS EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for LYRICA[®] (pregabalin) was originally approved on April 23, 2009, and REMS modifications were approved on January 4, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

As discussed in our teleconference on March 18, 2011, we have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS, and that a REMS is no longer necessary to ensure that the benefits of LYRICA[®] (pregabalin) outweigh its risks. Therefore, we agree with your proposal and a REMS for LYRICA[®] (pregabalin) is no longer required.

We remind you that the Medication Guide will continue to be a part of the approved labeling in accordance with 21 CFR Part 208.

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, contact Diana Walker, Ph.D., Regulatory Health Project Manager, at (301) 796-4029.

Sincerely,

{See appended electronic signature page}

Sharon H. Hertz, M.D.
Deputy Director
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:

Package Insert
Medication Guide
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SHARON H HERTZ
04/26/2011