NDA 022496/S-035

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Pacira Pharmaceuticals, Inc.
5 Sylvan Way, Suite 300
Parsippany, NJ 07054

Attention: Madhulika Joshi, MS, RAC
Associate Director, Regulatory Affairs

Dear Ms. Joshi:

Please refer to your supplemental new drug application (sNDA) dated and received May 22, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EXPAREL (bupivacaine liposome injectable suspension).

This Prior Approval sNDA proposes to expand the indication of EXPAREL to add patients aged 6 years to less than 17 years based on the results of pediatric postmarketing requirement study (PMR) 1834-5.

APPROVAL & LABELING

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

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated May 22, 2020, containing the final study report for the following postmarketing requirement listed in the September 19, 2019, postapproval postmarketing requirement letter for NDA 022496.

1834-5 A multicenter, randomized, open-label, IR bupivacaine-controlled (for subjects 12 to less than 17 years old) and single arm (for subjects 6 to less than 12 years old) study to evaluate the safety and pharmacokinetic profile of a single intraoperative administration of EXPAREL via infiltration for postoperative analgesia in a variety of surgical procedures in adolescent subjects 6 to less than 17 years old.

We have reviewed your submission and conclude that the requirement above was fulfilled.

We remind you that there are postmarketing requirements listed in the April 6, 2018, sNDA approval letter for NDA 022496/S-009 and the September 19, 2019, postapproval postmarketing requirement letter that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-*

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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 LCDR Mavis Y. Darkwah, PharmD, GWCPM, RAC-US, Regulatory Project Manager, at (240) 402-3158.

Sincerely,

{See appended electronic signature page}

Rigoberto Roca, MD
Director
Division of Anesthesiology, Addiction Medicine and Pain Medicine
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURES:
- Content of Labeling
  - Prescribing Information

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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