NDA 016964/S-082

SUPPLEMENT APPROVAL

Hospira, Inc.
275 North Field Drive
Building H1
Lake Forest, IL 60045

Attention: Kathleen Wang
Senior Associate, Global Regulatory Affairs

Dear Ms. Wang:

Please refer to your new drug application (NDA) dated and received on May 15, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MARCAINE (Bupivacaine Hydrochloride Injection, USP) and MARCAINE with Epinephrine (Bupivacaine Hydrochloride and Epinephrine Injection, USP).

We also refer to our approval letter dated August 21, 2020, which contained the following error: the concentration of MARCAINE with Epinephrine was inadvertently included as 1:20,000.

This replacement approval letter shows the proprietary and established names, and the correct concentration of MARCAINE with Epinephrine, which is 1:200,000. The effective approval date will remain August 21, 2020, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for conversion of the content of the prescribing information into Physician Labeling Rule (PLR) format.

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.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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 (text for the Prescribing Information), 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.

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).

In addition, submit amended labeling to your pending local anesthetic PLR conversion supplements aligning those proposed labels with the newly approved label for NDA 016964, MARCAINE / MARCAINE WITH EPINEPHRINE, as appropriate.

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-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]

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

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

We also remind you of your commitment, included in draft labeling submitted on August 6, 2020, to submit a supplement to your NDA proposing pediatric dosing information by July, 2021.

If you have any questions, call Taiye Adedeji, PharmD, Regulatory Project Manager, at (240) 402-8561.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information

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/

RIGOBERTO A ROCA
08/21/2020 12:00:00 AM