



NDA 021038/S-028

**SUPPLEMENT APPROVAL**

Hospira, Inc.  
275 North Field Drive  
Building H1-3S  
Lake Forest, IL 60045

Attention: Maria Hinklin  
Director, Pfizer Global Regulatory Affairs

Dear Ms. Hinklin:

Please refer to your supplemental new drug application (sNDA) dated August 28, 2015, and received October 21, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) Precedex (dexmedetomidine hydrochloride) in sodium chloride injection.

We acknowledge receipt of your amendment dated June 17, 2022, which constituted a complete response to our August 19, 2016, action letter.

This Prior Approval sNDA provides for revisions to the **USE IN SPECIAL POPULATIONS: Pediatric Use** section of the prescribing information, to include data from the pediatric MRI study conducted to satisfy the Pediatric Research Equity Act (PREA) requirement listed in the October 17, 2008, approval letter for supplement S-010:

- 1772-1    Deferred pediatric study under PREA for the treatment of sedation of nonintubated patients prior to and/or during surgical and other procedures in pediatric patients 0 to 16 years of age.

**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**

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

**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.<sup>1</sup> 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 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 *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

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).

**PREA PARTIAL WAIVER**

We also refer to your submission dated September 9, 2022, requesting a partial waiver of pediatric studies for pediatric patients less than 1 month of age. We are waiving the pediatric study requirement for ages from birth to less than 1 month because the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group **and** is not likely to be used in a substantial number of pediatric patients in this age group. We agree that non-sedate feed-and-swaddle methods are commonly used in this population for successful completion of MRI.

**FULFILLMENT OF POSTMARKETING REQUIREMENT**

Your submissions dated August 28, 2015, and June 17, 2022, contained the final report for the postmarketing requirement listed above. We have reviewed your submission(s) and conclude that the above requirement was fulfilled. We remind you that there is a postmarketing commitment listed in the March 13, 2013, approval letter for supplement S-020 that is still open.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> 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>.

## **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*.<sup>3</sup>

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.<sup>4</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>5</sup>

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety-related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

## **PATENT LISTING REQUIREMENTS**

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

## **REPORTING REQUIREMENTS**

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

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<sup>3</sup> For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

<sup>4</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>5</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

If you have any questions, email Rachel Jang, Regulatory Health Project Manager, at [Rachel.Jang@fda.hhs.gov](mailto:Rachel.Jang@fda.hhs.gov).

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

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

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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.**  
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/s/  
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RACHEL M JANG  
12/16/2022 04:37:54 PM

RIGOBERTO A ROCA  
12/16/2022 04:39:48 PM