

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### *APPLICATION NUMBER:*

**204957Orig1s000**

*Trade Name:*

*Generic or Proper Name:* Acetaminophen Injection, for IV Use

*Sponsor:* B. Braun Medical, Inc.

*Approval Date:* February 18, 2021

*Indication:*

Indicated for the

- Management of mild to moderate pain in adult and pediatric patients 2 years and older
- Management of moderate to severe pain with adjunctive opioid analgesics in adult and pediatric patients 2 years and older
- Reduction of fever in adult and pediatric patients

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## 204957Orig1s000

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*APPLICATION NUMBER:*

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**APPROVAL LETTER**

NDA 204957

**NDA APPROVAL**

B. Braun Medical, Inc.  
901 Marcon Blvd.  
Allentown, PA 18109

Attention: Cindy Katsempris  
Director, Regulatory Affairs

Dear Ms. Katsempris:

Please refer to your new drug application (NDA) dated and received December 13, 2016, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for acetaminophen injection, for intravenous use, 10 mg/mL.

We acknowledge receipt of your amendment dated August 27, 2020, which constituted complete responses to our April 24, 2020, action letter.

This new drug application provides for the use of acetaminophen injection for:

- Management of mild to moderate pain in adult and pediatric patients 2 years and older.
- Management of moderate to severe pain with adjunctive opioid analgesics in adult and pediatric patients 2 years and older.
- Reduction of fever in adult and pediatric patients.

### **APPROVAL & LABELING**

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

We note that your February 17, 2021, submission includes final printed labeling (FPL) for your Prescribing Information. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

### **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.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information) 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 via publicly available labeling repositories.

### **CARTON AND CONTAINER LABELING**

We acknowledge your November 4, 2020, submission containing final printed carton and container labeling.

### **DATING PERIOD**

Based on the stability data submitted to date, the expiry dating period for acetaminophen injection 10mg/mL, shall be 18 months from the date of manufacture when stored at 20 °C to 25 °C (68 °F to 77 °F) [see USP Controlled Room Temperature].

### **PROPRIETARY NAME**

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names*<sup>3</sup> and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022*.<sup>4</sup>)

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for

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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>.

<sup>3</sup> <https://www.fda.gov/files/drugs/published/Contents-of-a-Complete-Submission-for-the-Evaluation-of-Proprietary-Names.pdf>

<sup>4</sup> <https://www.fda.gov/media/99140/download>

the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

### **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>5</sup>

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.<sup>6</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>7</sup>

### **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 Jaimin Patel, Regulatory Project Manager, at (301) 796-0412.

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

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<sup>5</sup> For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

<sup>6</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>7</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

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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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RIGOBERTO A ROCA  
02/18/2021 03:44:04 PM