

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### ***APPLICATION NUMBER:***

**216903Orig1s000**

***Trade Name:*** Preveduo

***Generic or Proper Name:*** neostigmine methylsulfate and glycopyrrolate injection,

***Sponsor:*** Slayback Pharma LLC

***Approval Date:*** February 23, 2023

***Indication:*** for the reversal of the effects of nondepolarizing neuromuscular blocking agents (NMBA) after surgery, while decreasing the peripheral muscarinic effects (e.g., bradycardia and excessive secretions) associated with cholinesterase inhibition following NMBA reversal administration.

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## 216903Orig1s000

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*APPLICATION NUMBER:*

**216903Orig1s000**

**APPROVAL LETTER**



NDA 216903

**NDA APPROVAL**

Slayback Pharma LLC  
301 Carnegie Center  
Suite 303  
Princeton, NJ 08540

Attention: Praveen Subbappa  
Senior Director

Dear Mr. Subbappa:

Please refer to your new drug application (NDA) dated April 23, 2022, received April 25, 2022, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Preveduo (neostigmine methylsulfate and glycopyrrolate) injection, for intravenous use.

This NDA provides for the use of Preveduo for the reversal of the effects of non-depolarizing neuromuscular blocking agents (NMBAs) after surgery, while decreasing the peripheral muscarinic effects (e.g., bradycardia and excessive secretions) associated with cholinesterase inhibition following NMBA reversal administration.

### **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, submitted on February 22, 2023.

### **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

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

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 February 23, 2023, submission containing final printed carton and container labeling.

### **DATING PERIOD**

Based on the stability data submitted to date, the expiry dating period for Preveduo (neostigmine methylsulfate and glycopyrrolate) injection shall be 18 months from the date of manufacture when stored at 20-25 °C.

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

We are waiving the pediatric study requirement for ages birth to less than 2 years because there is evidence strongly suggesting that the drug product would be unsafe in this pediatric group. Because the blood pressure of neonates and infants is sensitive to changes in heart rate, the effects of an anticholinergic agent should be observed prior to administration of neostigmine to decrease the possibly to bradycardia followed by hypotension. Therefore, the combination of neostigmine and glycopyrrolate is not recommended for use in children less than 2 years of age.

This product is appropriately labeled for use in ages 2 to 17 years for this indication. Therefore, no additional studies are needed in this pediatric group.

### **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-*

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<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>.

*Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*<sup>3</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>4</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>5</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, contact Rita Joshi, PharmD, Regulatory Project Manager, at rita.joshi@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

**ENCLOSURES:**

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

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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>

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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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