



NDA 217569/S-003

## SUPPLEMENT APPROVAL

Baxter Healthcare Corporation  
Attention: Kirsten Hesemann  
Senior Manager, Global Regulatory Affairs  
25212 W. Illinois Route 120  
Round Lake, IL 60073

Dear Kirsten Hesemann:

Please refer to your supplemental new drug application (sNDA) dated and, received October 11, 2024, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vasopressin Injection USP in 0.9% Sodium Chloride.

This Prior Approval sNDA provides for revisions to the approved carton and container labels.

### **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.

### **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling submitted on December 13, 2024, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 217569/S-003**". Approval of this submission by FDA is not required before the labeling is used.

### **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).

If you have any questions, contact Lori Anne Wachter, RN, BSN, RAC – Drugs (US), Regulatory Project Manager for Safety, at 301 796-3975 or [lori.wachter@fda.hhs.gov](mailto:lori.wachter@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Mary Ross Southworth, PharmD,  
Deputy Director for Safety  
Division of Cardiology and Nephrology  
Office of Cardiology, Hematology, Endocrinology  
and Nephrology  
Office of New Drugs  
Center for Drug Evaluation and Research

#### ENCLOSURE(S):

- 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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MARY R SOUTHWORTH  
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