



Date: August 11, 2020

**URGENT: VOLUNTARY PRODUCT RECALL UPDATE**  
**Reclassification-Consumer/User Level**

Subject: **Desmopressin Acetate (Nasal Spray) 1.5 mg/mL**  
**Stimate®**  
**Batch Numbers: See chart below**  
**NDC Number: 0053-6871-00**

Dear Customer:

This updated letter is to provide you with additional information regarding the Stimate® Nasal Spray recall communication that was sent to you on July 21, 2020. Stimate® Nasal Spray is owned and manufactured by Ferring Pharmaceuticals, Inc., and distributed and sold by CSL Behring LLC. After further collaboration with FDA, Ferring is now extending this recall to the consumer/user level.

Ferring Pharmaceuticals US is voluntarily recalling all lots on the market of Stimate® Nasal Spray 1.5 mg/mL to the consumer level. This product is being recalled due to superpotency or amounts of desmopressin higher than specified. These out of specification results were identified during routine testing.

The risks associated with higher than specified amounts of desmopressin relate to abnormally low levels of sodium in the blood (i.e., hyponatremia) which could potentially lead to seizure, coma, and death. To date, Ferring has not received an increase in adverse event reports due to increased concentrations of desmopressin from users of the nasal spray. A single non-fatal adverse event potentially associated with this issue was reported in the US during the timeframe that the affected product was distributed.

Ferring is recalling all batches of Stimate® Nasal Spray. The table below provides detail for all impacted batches of Stimate® Nasal Spray that were shipped to CSL Behring beginning on December 15, 2017:

| Product  | NDC          | Batch    | Expiry Date |
|----------|--------------|----------|-------------|
| Stimate® | 0053-6871-00 | R15953C  | 30-Sep-22   |
|          |              | R14667A  | 31-Aug-22   |
|          |              | R14101A  | 31-Jul-22   |
|          |              | R13648A  | 30-Jun-22   |
|          |              | R13271A  | 30-Apr-22   |
|          |              | R11845A  | 30-Apr-22   |
|          |              | P13756P  | 31-Aug-21   |
|          |              | P13755A  | 30-Jun-21   |
|          |              | P13212H  | 30-Jun-21   |
|          |              | P13209L  | 30-Apr-21   |
|          |              | P11326C  | 28-Feb-21   |
|          |              | P11326AA | 28-Feb-21   |
|          |              | N17445N  | 31-Dec-20   |
|          |              | N15378G  | 30-Sep-20   |
|          |              | N14134C  | 31-Jul-20   |

This recall is to be conducted to the consumer level and is being conducted with the knowledge and approval of the Food and Drug Administration.

You have received an impacted batch:

- Notify all customers who received an impacted batch.
- Please complete the enclosed "Returned Goods Form," and return the completed form to the USFieldAction email/fax listed below.
- If you have inventory on hand, you will receive further return instructions from CSL Behring Customer Support.
- If you receive impacted batches from your customers, please contact CSL Customer Support for further instructions (see below for contact information for CSL Customer Support).
- Request your customers to distribute the enclosed Dear Patient Letter to all impacted patients.
- If you receive calls directly from an impacted patient, please have the patient contact My Source<sup>SM</sup>, CSL Behring's Patient Resource Center at 1-800-676-4266.

**Email: [USFieldAction@cslbehring.com](mailto:USFieldAction@cslbehring.com)**

**Fax: (610) 290-9390**

**PLEASE NOTE THAT RETURNS ARE LIMITED TO INVENTORY OF Stimate<sup>®</sup> batches listed in the table above ONLY. THERE WILL BE NO CREDIT GIVEN FOR RETURNS OF ANY OTHER BATCHES OF Stimate<sup>®</sup> THAT YOU HAVE IN INVENTORY OR RETURNED BY YOUR CUSTOMERS.**

**QUESTIONS:**

If you have any questions concerning inventory, return of affected material, and/or completion of the required "Returned Goods Form", please contact CSL Behring Customer Support.

**CSL Customer Support: Phone: 1-800-683-1288**

**Email: [customersupport@cslbehring.com](mailto:customersupport@cslbehring.com)**

If you have any questions concerning specifics of the recall, please contact CSL Behring Medical Information.

**CSL Medical Information: Phone: 1-800-504-5434**

**Email: [MedinfoNA@cslbehring.com](mailto:MedinfoNA@cslbehring.com)**

**If patients have questions regarding returns, please direct them to My Source<sup>SM</sup>, CSL Behring's Patient Resource Center:**

**My Source<sup>SM</sup>, CSL Behring's Patient Resource Center: Phone: 1-800-676-4266**

Thank you for your cooperation in this matter.

Sincerely,



Paul Stapel  
Director, Quality Assurance

Ferring Pharmaceuticals, Inc.  
CSL Behring



Brian Puglisi, PharmD  
Quality Assurance Manager  
Global Quality  
CSL Behring, L.L.C