



Date: July 21, 2020

## URGENT: VOLUNTARY PRODUCT RECALL

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

Dear Customer:

This letter is to inform you of a recall of Stimate® which is owned and manufactured by Ferring Pharmaceuticals, Inc., and distributed and sold by CSL Behring LLC.

Ferring Pharmaceuticals Inc. is initiating a precautionary voluntary recall of all batches of Stimate® Nasal Spray (desmopressin acetate) 1.5 mg/mL. During testing of a sample of desmopressin acetate nasal spray solution product marketed outside the US, a low volume was observed and the analysis of the solution from this sample generated an out-of-specification result concerning the desmopressin content (155% of the targeted amount). In addition, an elevated amount of benzalkonium chloride was determined (120% of the targeted amount).

A Health Hazard Safety Evaluation has been prepared by Ferring. There is a reasonable probability that the use of, or exposure to, certain defective units of this product could pose a significant hazard and may cause adverse health consequences due to increased concentrations of desmopressin.

The table below provides detail for all impacted batches of Stimate® 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

You have received an impacted batch:

- Please complete the enclosed "Returned Goods Form," and return the completed form to the email/fax listed below.
- If you have inventory on hand, you will receive further return instructions from CSL Behring Customer Support.

**Email: [USFieldAction@cslbehring.com](mailto:USFieldAction@cslbehring.com)**  
**Fax: (610) 290-9390**

**PLEASE NOTE THAT RETURNS ARE LIMITED TO INVENTORY OF Stimate® batches listed in the table above ONLY. THERE WILL BE NO CREDIT GIVEN FOR RETURNS OF ANY OTHER BATCHES OF Stimate® 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)**

Thank you for your cooperation in this matter.

Sincerely,



Paul Stapel  
Director, Quality Assurance  
[Ferring Pharmaceuticals, Inc.](#)



Brian Puglisi, PharmD  
Quality Assurance Manager  
Global Quality  
[CSL Behring, L.L.C](#)