FERRING
PHARMACEUTICALS

CSL Behring
Biotherapies for Life®

Date: August 12, 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 obtained 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.

We previously asked you to do the following, if 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
Fax: (610) 290-9390

We are requesting you take the following actions:

- Send the enclosed Dear Patient Letter to any patient that received the impacted product.
- Patient Returns will be handled directly through My Source℠, CSL Behring's Patient Resource Center (contact information below).

If patients have questions regarding returns or reimbursement, please direct them to My Source℠, CSL Behring's Patient Resource Center:

My Source℠, CSL Behring's Patient Resource Center: Phone: 1-800-676-4266.

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

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

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

CSL Behring