Dr. Leonard Valentino
President and CEO
National Hemophilia Foundation

Sharon Meyers, EdD, CFRE
President and CEO
Hemophilia Federation of America

Dear Dr. Valentino and Dr. Meyers:

Thank you for your letter and your commitment in support of patients affected by hemophilia and other inherited bleeding disorders. Please see the joint response below from Ferring Pharmaceuticals Inc. ("Ferring") and CSL Behring, LLC ("CSL Behring").

Stimate® (desmopressin acetate, 1.5 mg/1 mL) Nasal Spray is owned and manufactured by Ferring, and distributed and sold by CSL Behring. As you are aware, Ferring has issued a voluntary retail level recall of Stimate. We are working closely with the U.S. Food & Drug Administration (FDA) on the recall.

Reason for the recall
Ferring issued a voluntary retail level recall of Stimate® (desmopressin acetate, 1.5 mg/1 mL) Nasal Spray after routine testing obtained out-of-specification assay results in some vials of desmopressin nasal spray product marketed outside the US. The assay identified the potential for higher concentrations of desmopressin in some vials. The root cause of the deviation is under investigation.

While there is a reasonable probability that the continued use of certain defective units of this product could pose a health hazard and may cause adverse consequences due to increased concentrations of desmopressin, to date Ferring and CSL Behring have not received an increase in adverse event reports due to increased concentrations of desmopressin from users of the nasal spray. Exposure to an increased amount of desmopressin can cause water retention and hyponatremia (decrease of sodium concentration in the blood). Please note that this issue does not affect any dosage forms of Ferring desmopressin other than the nasal spray.

To safeguard patients, Ferring and CSL Behring have in place comprehensive pharmacovigilance systems for collection of adverse event reports for Stimate from post marketing sources. This enables real time and periodic medical assessment of single and aggregate safety data and appropriate signal detection

and evaluation activities to ensure the safety profile of the product is adequately characterized and appropriate risk minimization strategies are implemented.

Recall process and communications

Ferring and CSL Behring are following all FDA guidelines governing a product recall within the United States. To ensure all those who may be impacted by the recall are fully informed and in accordance with FDA guidelines, we have deployed several communications within the US. All communications were initiated immediately upon receipt of FDA approval. These include a combination of letters, emails, and phone calls to purchasers and HCPs who have requested a Stimate sample, as well as patient advocacy organizations. Alerts through the PPTA Patient Notification System have also been initiated. Ferring and CSL Behring acknowledge the concern and hardships this presents for patients, physicians and pharmacists, and will keep the community apprised of the situation so that therapy management decisions can be made with the best available information.

Our commitment to patient care continues to be a key priority and guiding principle for Ferring and CSL Behring, and it is our goal to manage supply so that patients experience minimal disruption. We encourage patients to contact their pharmacy regarding their individual prescription and, if necessary, contact their healthcare provider about their treatment plan. Any patient or caregiver with concerns regarding further use of this product or alternatives to Stimate should contact their healthcare provider for guidance, as they are the best resource to answer individualized treatment related questions. Neither Ferring nor CSL Behring are able to make medical treatment recommendations regarding options for individual patients.

Recalled lots
The recall involves the following lots:

Lot	Exp Date	NDC #
Stimate® Nasal Spray 1.5 mg/1 mL, 2.5 mL		
N14134C	07 2020	0053-6871-00
N15378G	09 2020	0053-6871-00
N17445N	12 2020	0053-6871-00
P11326AA	02 2021	0053-6871-00
P11326C	02 2021	0053-6871-00
P13209L	04 2021	0053-6871-00
P13212H	06 2021	0053-6871-00
P13755A	06 2021	0053-6871-00
P13756P	08 2021	0053-6871-00
R11845A	04 2022	0053-6871-00
R13271A	04 2022	0053-6871-00
R13648A	06 2022	0053-6871-00
R14101A	07 2022	0053-6871-00
R14667A	08 2022	0053-6871-00
R15953C	09 2022	0053-6871-00

Future availability
We do not currently have a timeline for availability of new product. There are, however, other dosage forms of desmopressin acetate on the market as well as other options potentially available for patients. Healthcare providers can contact their pharmacies and/or the manufacturers of these dosage forms for information about the availability of these alternatives.

Thank you again for your concern and work on behalf of patients. We share your commitment.

Paul Stapel
Director, Quality Assurance

Ferring Pharmaceuticals, Inc.

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

Stimate Important Safety Information

Stimate® (desmopressin acetate) Nasal Spray, 1.5 mg/mL is a treatment used to stop some types of bleeding in people with mild hemophilia A or mild to moderate von Willebrand disease (VWD) Type 1.

Stimate Nasal Spray should not be used in children under 11 months of age. All patients using Stimate Nasal Spray are at risk of water intoxication, fluid overload and low sodium levels in the blood. Follow your healthcare provider's instructions on limiting the amount of fluid you drink when using Stimate Nasal Spray, as too much fluid intake can lead to serious adverse reactions, including seizures, coma, and even death. Fluid restrictions are especially important for children and elderly patients, as they are at higher risk for these reactions.

See the patient information leaflet in the prescribing information for Stimate Nasal Spray for symptoms that could mean your blood sodium level is low—including headache, hallucinations, confusion, restlessness, weight gain and muscle spasms. Immediately report any of these symptoms to your physician or, if necessary, an emergency department. Also contact your doctor immediately if you have uncontrolled bleeding.

Before being prescribed Stimate Nasal Spray, make sure your doctor knows about all your medical conditions and about any medications you are taking. Use Stimate Nasal Spray exactly as your healthcare provider has instructed.

Side effects of Stimate Nasal Spray generally come from having too much water in the body. The most common include facial flushing, nasal congestion, runny nose, nose bleed, sore throat, cough, and upper respiratory infections. Tell your healthcare provider if you experience a side effect that does not go away.

Please see full prescribing information for Stimate Nasal Spray, which includes the patient information leaflet.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

You can also report side effects to CSL Behring's Pharmacovigilance Department at 1-866-915-6958.