

Brian Puglisi, PharmD
Quality Assurance Manager
Global Quality
CSL Behring, LLC

Paul Stapel
Director, Quality Assurance
Ferring Pharmaceuticals, Inc

Re: Pharmacy-Level Recall of desmopressin nasal spray (Stimate)

Dear Mr. Puglisi and Mr. Stapel,

The National Hemophilia Foundation (NHF) and Hemophilia Federation of America (HFA) are national nonprofit organizations that represent individuals with bleeding disorders across the United States. Our missions are to ensure that individuals affected by hemophilia and other inherited bleeding disorders have timely access to quality medical care, therapies, and services, regardless of financial circumstances or place of residence. Both organizations accomplish this through advocacy, education, and research.

We are writing concerning the [announced recall](#) of desmopressin nasal spray (Stimate) manufactured by Ferring Pharmaceuticals and licensed and distributed in the U.S. by CSL Behring. The recall, which is due to out-of-specification levels of the active ingredient, is deeply disturbing – particularly since Ferring has issued a Health Hazard Safety Evaluation, warning that certain defective units of the product could “pose a significant hazard and may cause adverse health consequences due to increased concentrations of desmopressin.” Beyond this alarming defect, and the fact that the affected lots appear to have been distributed as early as December 2017 – more than 2.5 years ago – we are also troubled by the fact that U.S. customers are learning of the recall **10 days later** than their counterparts in countries such as Brazil and Singapore.

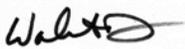
With this letter, NHF and HFA are initiating an ongoing dialogue so that our organizations can inform the patients we represent about the reasons for the recall, your proposed strategy for handling the recall, and implications for patients who use the product now and in the future. We have some immediate questions for CSL Behring and Ferring and ask that you respond to these questions in writing as quickly as possible.

1. Please describe the specific nature of the product deviation. If only certain lots were affected, please specify which lots, quantify how many vials were affected, and describe how many affected vials were distributed in the U.S.
2. What is the basis for Ferring’s preparation of a Health Hazard Safety Evaluation and its warning that [“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”](#)?
3. Have Ferring and/or CSL Behring received notice of any adverse events affecting patients who used the product, either in the U.S. or overseas? What would be the potential medical implications for patients who have used or continue to use defective units?
4. Please describe, specifically and in chronological order, how and when the product deviation was discovered, and what steps are being taken to correct the deviation and prevent it from recurring.
 - a. During what time period were the affected products manufactured?
 - b. Please provide a detailed timeline with dates of

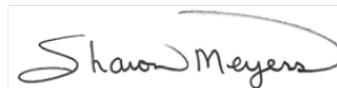
- i. Ferring's discovery of the product deviation
 - ii. Ferring's notification of CSL Behring that there was a problem with the product
 - iii. Ferring's notification of the U.S. Food and Drug Administration
 - iv. Ferring's and/or CSL Behring's notification of U.S. recipients
5. Has Ferring halted production of the product?
 - a. If yes, do you expect that production will resume? When?
 - i. When would U.S. distribution resume?
 - b. Has Ferring and/or CSL Behring notified the FDA of possible shortages of the product?
6. What actions are Ferring and/or CSL Behring taking to accomplish the recall as well as ensure that patients in the U.S. receive timely notification of the recall?
 - a. Please explain why CSL Behring and/or Ferring determined that a pharmacy-level recall would be the appropriate level of recall in this instance.
 - b. Does a pharmacy level recall mean that Ferring and/or CSL Behring will take no steps to identify and/or notify affected patients?
 - c. How and to whom should patients return the product? Have pharmacies been provided with instructions on how and where to return affected product?
 - d. Has Ferring and/or CSL Behring submitted notice of the recall to the Patient Notification System (PNS)? If so, when will the PNS notification be distributed? If Ferring and/or CSL Behring do not plan to activate the PNS, why not?
 - e. Please describe how Ferring and/or CSL Behring are announcing the recall and explain your reasons for using different modalities (e.g. email vs. FedEx) to contact different groups of stakeholders.
7. What, if any, medical guidance is Ferring and/or CSL Behring providing to U.S. health care providers and pharmacies? We request that you provide us with copies of all communications between either of your companies and health care providers and/or pharmacies regarding the product recall.
 - a. Are you recommending any specific laboratory testing?
 - b. Are you recommending that patients transition to another treatment?
8. Based on available website information, recalls were announced in other countries as early as July 10, 2020. Why did it take so long to notify patients in the U.S.?

We look forward to your prompt response with answers to these questions. We hope to keep open lines of communication as this situation develops. Please contact Nathan Schaefer, Vice President of Public Policy for NHF (nschaefer@hemophilia.org) and Sonji Wilkes, Senior Director of Policy, Advocacy and Government Education for HFA (s.wilkes@hemophiliamed.org) to schedule a call to respond to our questions.

Sincerely,



Dr. Leonard Valentino
President and CEO
National Hemophilia Foundation



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