



Dr. Leonard Valentino
President and CEO
National Hemophilia Foundation

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

February 3, 2021

Stimate[®] (desmopressin acetate, 1.5 mg/1 mL) Nasal Spray

Dear Dr. Valentino and Ms. Meyers,

I am writing to follow up on our letter to you, dated July 30, 2020, regarding the availability of Stimate[®] (desmopressin acetate, 1.5 mg/1 mL) Nasal Spray (“Stimate”). As you know, in July 2020, Ferring issued a voluntary 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.

We have completed our investigation and have identified the underlying cause for the out-of-specification results as an issue with the tightness of the seal of the bottle.

Future Availability

To prevent a reoccurrence of this issue, Ferring intends to procure, install and qualify a new production line. Based on the time required to complete these tasks, we anticipate that we will be able to restart manufacturing of Stimate[®] (desmopressin acetate, 1.5 mg/1 mL) Nasal Spray in Q2 of 2023. Contingent on FDA approval, we estimate first deliveries to the market will be possible in the second half of 2023.

Alternatives for Patients

Please note that there are 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 marketed products for information about the availability of these alternatives.

Ferring is committed to ensuring that our medicines adhere to the highest quality standards for our patients. When more concrete information on the return to market timing is available for Stimate, we will update you.

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

Best regards,

A handwritten signature in blue ink, appearing to read 'J. Tursi', is positioned below the text 'Best regards,'.

James Tursi, MD
Chief Scientific Officer
Ferring Pharmaceuticals U.S.