Date : March 17, 2022

URGENT: VOLUNTARY DRUG RECALL

Depth of Recall: Distributor/Wholesaler/Healthcare Providers

NDC Number: 71104-810-01

Product Description	Lot #	Expiration Date
ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] 6000 IU	**SP2113**	**30JUN2023**

To Whom It May Concern,

This letter is to inform you that Sanofi is initiating as a precautionary measure a **voluntary recall** of one lot of ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] **6000 IU**. This product is labeled as manufactured by Bioverativ Therapeutics Inc. Bioverativ Therapeutics is a Sanofi company.

Product from this single lot displays the incorrect potency value of 6641 IU on the carton, product kit, and vial label. The correct potency value is 6747 IU.

The overall risk to patient safety is anticipated to be low given the difference between the actual and mislabeled potency of this lot of 6000 IU vials.

No other product lots are involved in this recall.

Our records indicate that you have received product from the above listed lot. Distribution of this lot by Sanofi started on February 1, 2022 and ended on March 8, 2022.

Required Actions:

1. **Immediately discontinue use and distribution of the above listed lot number of ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein] 6000 IU.**
2. **Please notify any of your customers who have received this ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion**

Protein] 6000 IU lot, and instruct them to discontinue use of and return all product from this lot.

3. **Complete the enclosed Business Reply Card after you have finished checking your inventory and notifying your accounts.**
4. **Please return all unused product by contacting Inmar Intelligence at 1-800-967-5952.**

Please return the Business Reply Card indicating whether you have remaining product or not. Your response will help to ensure that all existing stock of this lot has been returned. If you prefer to fax this information, the number is 1-817-868-5362, or E-mail rxrecalls@inmar.com

Sanofi will issue you a credit upon receipt of the recalled product by Inmar Intelligence.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. Your assistance with this product recall is greatly appreciated. Direct Accounts may contact Sanofi US Trade Support at 1-855-489-3228 if you require additional information, or to place a new product order.

All questions of a medical or clinical nature should be sent to Sanofi Medical Information Services in the U.S. at 1-800-633-1610, option 1.

Sincerely,

Allison Steele

Electronically signed by: Allison Steele
Reason: Signature applied
Date: Mar 17, 2022 13:33 EDT

Allison Steele
Recall Lead, North America Quality