Bayer – Recall of Kogenate® FS antihemophilic factor (recombinant)

- On July 19, 2019, Bayer announced a consumer-level recall of two lots of Kogenate® FS antihemophilic factor (recombinant) 2000 IU vials because some of these vials contained Jivi® antihemophilic factor (recombinant) PEGylated-aucl 3000 IU.

- The recalled lots were distributed from February 5, 2019 to July 15, 2019.

Product Description	NDC#	Lot# (Expiration Date)
Kogenate FS antihemophilic factor (recombinant) 2000 IU vials	0026-3786-65	27118RK (6/12/2021); 27119CG (6/12/2021)

- Kogenate FS and Jivi are both used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A. Kogenate FS is approved to treat or control bleeding in adults and children with hemophilia A. Jivi is approved to treat and control bleeding in previously treated adults and adolescents (12 years of age and older) with hemophilia A.

- While the majority of the mislabeled vials in the affected lots were recovered, approximately 990 of these vials were released in the U.S. The associated Jivi batch was expired as of August 2018. However, all stability specifications of this expired Jivi batch had continued to be met, as of April 2019.

- Bayer has voluntarily recalled both lots of Kogenate in the interest of patient safety, and to ensure that any potentially impacted product is removed from pharmacy shelves, and that patients and their healthcare providers are alerted.

- Importantly, vials of Kogenate FS that are not associated with the affected lot numbers are not impacted and can continue to be used without interruption. There are no lots of Jivi or Kovaltry® antihemophilic factor (recombinant) product affected by this recall.

- Patients in possession of vials from the affected lot numbers should immediately stop using the product and contact their physician. In addition, patients should contact their pharmacy to return the affected product.

- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled Kogenate FS.

- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.

- For more information regarding this recall, contact Bayer at **1-888-842-2937**.