IMPORTANT: VOLUNTARY DRUG RECALL EXTENSION

Bayer initiates voluntary recall extension for Kogenate® FS Antihemophilic Factor (Recombinant)

August 11, 2016

Dear Kogenate® FS Customer,

This letter is a follow-up to the communication sent to you on July 21, 2016 regarding a voluntary recall of two lots of hemophilia A drug Kogenate® FS containing active ingredient manufactured before November 2015. The lots communicated on July 21, 2016 are:

Product	Lot Number	NDC Number	Expiry Date
KOGENATE FS 2000 IU VIAL ADAPTER	270R978	0026-3786-65	09/17/2017
KOGENATE FS 2000 IU VIAL ADAPTER	270TN1C	0026-3786-65	06/06/2018

Bayer has conducted an analysis of additional lots with active ingredient manufactured before November 2015 to determine if there was a need for further action. The analysis is now complete and, as a result, we are voluntarily recalling additional lots.

Routine stability testing showed potency is declining faster than expected in these lots, which is why the recall is being conducted. The material is packaged in 5mL glass vials and comes in a shelf carton with either a BIO-SET or vial adapter as indicated in the tables below.

In two lots distributed between May 19, 2014 and February 23, 2015, potency levels fell below the pre-specified acceptable range. These two lots are:

Product	Lot Number	NDC Number	Expiry Date
KOGENATE FS 2000 IU VIAL ADAPTER	270PWG8	0026-3786-65	05/08/2017
KOGENATE FS 3000 IU BIO-SET	270NPV2	0026-3797-70	08/17/2016

In eight lots distributed between June 9, 2015 and August 2, 2016, potency may eventually fall below the pre-specified acceptable range before shelf life expiry. These lots are listed in a table on page two ("Additional Lots Subject to Recall").

It is important to note that based on all currently available and reviewed data that no safety observations or signals have been detected by Bayer's drug safety group and the current health risk assessment does not indicate an appreciable risk for patients for the affected lots.

Additional Lots Subject to Recall:

Product	Lot Number	NDC Number	Expiry Date
KOGENATE FS 250 IU VIAL ADAPTER	270RV8X	0026-3782-25	12/19/2017
KOGENATE FS 250 IU VIAL ADAPTER	270TN10	0026-3782-25	06/04/2018
KOGENATE FS 500 IU VIAL ADAPTER	270R70V	0026-3783-35	08/27/2017
KOGENATE FS 500 IU VIAL ADAPTER	270RJ5L	0026-3783-35	11/23/2017
KOGENATE FS 500 IU VIAL ADAPTER	270T306	0026-3783-35	01/29/2018
KOGENATE FS 500 IU VIAL ADAPTER	270TG7L	0026-3783-35	03/25/2018
KOGENATE FS 1000 IU VIAL ADAPTER	270TW0R	0026-3785-55	07/8/2018
KOGENATE FS 3000 IU VIAL ADAPTER	270TTR6	0026-3787-75	06/22/2018

Bayer is initiating a retail level voluntary recall*. As such, we ask that you please:

- immediately quarantine inventory of the affected product under your direct control
- immediately contact your retail (pharmacy) level customers to have the identified product removed from pharmacy inventories and returned to you
- complete the attached business reply card and follow the instructions to arrange for return of the identified product from your current inventory and returns coming from your retail level customer base
- contact Genco Pharmaceutical Solutions toll-free at 1-855-838-5782

Bayer is committed to minimizing any potential disruption in product supply. If you have questions related to replenishment, please call 1-888-606-3780. For other inquiries, please call 1-888-84-BAYER (1-888-842-2937).

Sincerely,

Tom Lupo
Bayer Quality Representative

** Retail level recall: product recall to the level immediately preceding the consumer or patient level; includes retail and hospital pharmacies.*