September 27, 2019

Mr. Val Bias
Chief Executive Officer
National Hemophilia Foundation

Ms. Kimberly Haugsted
President & CEO
Hemophilia Federation of America

Dear Val and Kimberly,

We are grateful for your partnership and commitment to ensuring the community receives the most current information regarding the July 19th recall of select lots of Kogenate® FS antihemophilic factor (recombinant). We realize members of the community continue to have questions and we are committed to working with your organizations to provide the information needed to help alleviate any current and future concerns.

As we have communicated previously, we are taking the necessary and appropriate actions to address the root cause of the recall, which includes making significant procedural and process enhancements to prevent the possibility of this event occurring again. In addition, Bayer holds our people accountable to maintain the highest standards for quality and performance. Accordingly, the individuals directly involved in this incident are no longer employed by Bayer.

We appreciate the opportunity to respond to questions included in your most recent letter sent to Bayer (received on September 23, 2019) on behalf of the NHF and HFA. In this correspondence, the NHF and HFA have proposed that Bayer work with these organizations on several levels, including to:

Q1: Convene a Product Safety Summit in first quarter 2020. We ask that you continue your conversations with our senior staff as they work toward finalizing a timetable, agenda, and other details for this summit.

Patient safety is Bayer's highest priority. As a strong partner to the hemophilia community, Bayer looks forward to working together to hold a Product Safety Summit to identify ways to continue to improve both product and patient safety. Bayer takes its 30-year partnership with the hemophilia community very seriously, and we remain deeply dedicated to meeting the needs of patients.

Q2: Follow up on your letter of August 22, in which Bayer said it would share information about patients under 12 years of age who received the mixed-up product and adverse events reported to Bayer. Bayer also said that it would "inform the community of any safety signals that emerge through continued monitoring." Please advise us of the timeframe within which you expect to complete your evaluation. Please share any interim or preliminary data that you can make available at this time.

Since the July 19th voluntary recall of two lots of Kogenate FS, we have been continuously monitoring for any complaints or adverse event reports that may be related to this recall, especially in children 12 years of age and younger who may have received affected product. Bayer has been, and continues to be, timely and transparent in our reporting of any safety signals and adverse events associated with the recall. A safety report covering the time period from January 31, 2019 through September 13, 2019 is attached.

Q3: Consider establishing a patient portal on your website where you can post safety updates on an ongoing basis.

Bayer welcomes community feedback on ways to improve engagement and communication, especially around important product safety issues. Currently, all Kogenate FS product recall-related information and safety updates are posted on a dedicated homepage screen on the Kogenate FS product website. This information is also available on the Bayer US corporate website in the special statements section of the newsroom.

Kind regards,

Paul Bedard
Senior Vice President, Specialty Franchise

Aleksandra Vlajnic M.D., MBA
Senior Vice President, U.S. Medical Affairs

Kogenate® FS antihemophilic factor (recombinant)

Indications and Important Safety Information

Indications

Kogenate® FS Antihemophilic Factor (Recombinant) is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A.

Kogenate FS is used to treat and control bleeding in adults and children with hemophilia A. Your healthcare provider may give you Kogenate FS when you have surgery.

Kogenate FS can reduce the number of bleeding episodes in adults and children when used regularly (prophylaxis). Kogenate FS can reduce the risk of joint damage in children without pre-existing joint damage when used regularly.

Kogenate FS is not used to treat von Willebrand disease.

Important Safety Information

You should not use Kogenate FS if you are allergic to rodents (like mice and hamsters) or are allergic to any ingredients in Kogenate FS.

Tell your healthcare provider if you have been told you have heart disease or are at risk for heart disease.

You could have an allergic reaction to Kogenate FS. Call your healthcare provider right away and stop treatment if you get rash or hives, itching, tightness of the chest or throat, difficulty breathing, light-headed, dizziness, nausea or a decrease in blood pressure.

Your body can make antibodies, called “inhibitors,” against Kogenate FS, which may stop Kogenate FS from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.

Other common side effects of Kogenate FS are local injection site reactions (pain, swelling, irritation at infusion site) and infections from implanted injection device. Tell your healthcare provider about any side effect that bothers you or does not go away.

Call your healthcare provider right away if bleeding is not controlled after using Kogenate FS.

For important risk and use information, please see full prescribing information.