Important Information for the Hemophilia Community Regarding Triad Group's Alcohol Prep Products and Bayer's BayCuff™ and First Aid Kit

January 10, 2011

Dear Bayer Customer:

Bayer HealthCare Pharmaceuticals has become aware of a broad United States market recall of alcohol prep pads, swabs and swabsticks manufactured by the Triad Group and marketed under various brand names. In the interest of patient safety, Bayer wants to ensure that you are aware that two service items provided by Bayer to the hemophilia community, BayCuff™, a self-infusion training program, and a First Aid Kit include Triad alcohol prep pads.

It's important to note that **Kogenate® FS, antihemophilic factor (recombinant),** product packaging **does not** contain any Triad Group alcohol prep products.

The recall of the Triad Group alcohol prep products is due to potential contamination of these products with the bacteria, Bacillus cereus, that could lead to life-threatening infections. Further information on this Triad recall can be found on the U.S. Food and Drug Administration (FDA) website at http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm239319.htm.

Bayer instructs patients to immediately discontinue using the Triad alcohol prep pads and dispose of both the BayCuff™ and First Aid Kits in the trash.

If you have additional questions, please consult with your pharmacist or healthcare provider. Or call Bayer at 1-888-84-BAYER (22937), where operators are available 24 hours a day to respond to questions.

Bayer is currently in the process of gathering additional information from both Triad and the FDA. In the interim, we have stopped distribution of the BayCuff™ self-infusion training program and First Aid Kits, until we can affect a replacement for the alcohol prep pad. If you would like to get a replacement of these service items once new alcohol prep pads are available, please contact your local Bayer representative at 1-888-84-BAYER (22937).

INDICATIONS & USAGE

Kogenate® FS, antihemophilic factor (recombinant), is a recombinant factor VIII treatment indicated for the control and prevention of bleeding episodes and peri-operative management in adults and children (0-16 years) with hemophilia A. **Kogenate® FS** is also indicated for routine prophylaxis to reduce the frequency of bleeding episodes and the risk of joint damage in children with hemophilia A with no preexisting joint damage.

IMPORTANT SAFETY INFORMATION

The most serious adverse reactions are systemic hypersensitivity reactions and the development of high-titer inhibitors necessitating alternative treatments to AHF. The most common adverse reactions observed in clinical trials were inhibitor formation in previously untreated or minimally treated patients, skin-associated hypersensitivity reactions, infusion site reactions, and central venous access device (CVAD) line-associated infections.

Kogenate® FS is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including mouse or hamster proteins.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/**medwatch**, or call 1-800-FDA-1088.

For important risk and use information, please see the full prescribing information available at www.kogenatefs.com.

Sincerely,

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