Bayer

Pharmaceutical Division

Biologicals Business Unit

Carol M. Moore
Vice President
Quality Assurance/Regulatory Affairs
Responsible Head/Agent

July 27, 2000

Re: Urgent Withdrawal of Kogenate® Lot Numbers 670H071C and 670H076

Dear Health Care Provider,

I am writing to inform you that Bayer Corporation has voluntarily decided to withdraw Kogenate Antihemophilic Factor (Recombinant) lot numbers 670H071C and 670H076.

Bayer routinely performs quality assurance testing to assure the stability of our Antihemophilic Factor (Recombinant) product. During such testing we became aware of a potential problem relating to our quality assurance release test for rFVIII potency. After extensive investigation it was determined that these two lots were tested for Factor VIII potency using the reagent, known as Severe Hemophilic Plasma that was determined to be the cause of variable potency. A routine investigation of the test procedure revealed that if the product from these two lots are stored at room temperature (25°C) for up to three months, the potency could drop below acceptable levels. However the potency continues to remain stable when product is refrigerated. Further investigation has confirmed that the cause is not related to a stability issue with the product but is attributed to this Severe Hemophilic Plasma reagent used during initial testing. Specifically Bayer has determined that this reagent resulted in the designation of an artificially high potency value at release for these two lots.

As of this date there have been no adverse events reported in association with these lots.

Healthcare professionals should report any serious adverse events suspected to be associated with the use of Kogenate to Bayer Clinical Communications at 1-800-288-8371. Alternatively, this information may also be reported ot the FDA's MedWatch reporting system by phone (1-800-FDA-1088), facsimile (1-800-FDA-0178), online https://www.accessdata.fda.gov/scripts/medwatch/) or mailed, using the MedWatch form FDA 3500, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787.

Bayer is requesting your cooperation in the return of the above-mentioned lots as a precautionary measure. Please examine your stock and immediately determine if you have any of the above-mentioned lots on hand and, if so, cease use and return them to the address below. If you have further distributed product, you must send notification of this withdrawal to your customers.

Withdrawal Coordinator (N. Londeree)
Bayer Corporation
800 Dwight Way
Berkeley, CA 94710

You will be credited for your returned goods and associated shipping charges. If you have any questions regarding the return of the product please contact Bayer Customer Service 1-800-288-8370.

Sincerely,

Carol Moore, Vice President
Quality Assurance/Regulatory Affairs
Responsible Head/Agent
Bayer Corporation

Bayer Corporation
800 Dwight Way
P.O. Box 1986
Berkeley, CA 94701-1986
Phone: 510 705-5224
Fax: 510 705-4712