

Aventis Behring



August 1, 2000

URGENT: BIOLOGIC WITHDRAWAL

Re: **Withdrawal of Helixate® Lot No. 670H071E**

Dear Health Care Provider,

I am writing to inform you that Aventis Behring L.L.C. has voluntarily decided to withdraw Antihemophilic Factor (Recombinant) Helixate® lot number 670H071E manufactured by Bayer for Aventis Behring.

This lot of Helixate® was tested for Factor VIII potency using a reagent, known as FVIII-deficient plasma. During a routine quality assurance investigation of the testing procedure, Bayer learned that Lot 670H071E may not maintain its labeled potency if held at room temperature (25°C) for 3 months. However, the product will remain stable if stored at 2-8°C. Further investigation has confirmed that the cause is not related to a stability issue with the product but is attributed to the reagent used during initial testing. Specifically, Bayer has determined that the FVIII deficient plasma reagent resulted in the designation of an artificially high potency value at release.

As of this date, there have been no adverse events reported in association with this lot of Helixate®.

Healthcare professionals should report any serious adverse events suspected to be associated with the use of Helixate® to the Drug Surveillance Department at Aventis Behring at 1-610-878-4192. Alternatively, this information may also be reported to the FDA's MedWatch reporting system by phone (1-800-FDA-1088), facsimile (1-800-FDA-0178), online at <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.

If you or your patients have any Helixate® from lot number 670H071E, it should be returned to Aventis Behring. Customers who purchased this product directly from Aventis Behring will be credited for every returned vial of Helixate® only from lot 670H071E, and Aventis Behring shall bear shipping costs. Customers who purchased through a distributor will be credited through their distributors. Please contact the Customer Support Department at 1-800-683-1288 for return and shipping information. Additional details are available on the Aventis Behring website, <http://www.aventisbehring.com/na>.

If you have any further questions, please feel free to contact:

- Your local Aventis Behring representative
- The Customer Support Department at 1-800-683-1288

We sincerely regret any inconvenience that this has caused. We appreciate your understanding, and look forward to working closely with you in the future.

With best regards,

A handwritten signature in blue ink that reads "Martin D. Phillips" with a stylized flourish at the end.

Martin D. Phillips, M.D.
Senior Medical Director