

# Cutter

August 9, 1985

Elaine C. Esber, M.D.  
Director  
Office of Biologic Research and Review  
Center for Drugs and Biologics  
Parklawn Bldg. HFN-825  
5600 Fishers Lane  
Rockville, MD 20857

FACTOR IX COMPLEX PLA  
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Re: Antihemophilic Factor (Human)  
Factor IX Complex

Dear Dr. Esber:

On June 21, 1985, Cutter Biological discontinued distribution and manufacture of all non-heat-treated Factor VIII and Factor IX products. A letter was sent to each of our customers recommending that they review their product inventory and return all non-heat-treated material to Cutter. This action followed an earlier decision on October 26, 1984, when we indicated that we were planning to discontinue any additional manufacture of non-heat-treated Factor VIII.

In addition to the voluntary action we have taken to convert all coagulation product distribution to heat treat, we are formally advising you that Cutter Biological warrants that we will not manufacture or distribute any non-heat-treated Factor VIII [Antihemophilic Factor (Human)] or Factor IX [Factor IX Complex].

This action should not be construed as any determination of the safety of non-heat-treated Koate® or Konbyte®.

Our research efforts are on-going with regard to viral inactivation both within the manufacturing process as well as by process modifications. Future products, including rDNA Factor VIII, will be evaluated for the most suitable method of viral inactivation with the intent of making the safest possible product.

Please do not hesitate to contact us if we can provide any further information on this issue.

Sincerely,

GRO-C

Steven J. Ojala, Ph.D.  
Director, Regulatory Affairs

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