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NATIONAL DRUGS ADVISORY BOARD  
AN BÓRD COMHAIRLEACH NAISIÚNTA DRUGANNA  
63-64 ADELAIDE RD., DUBLIN 2.  
TEL: 764971/7 TELEX: 90542

MR/HM

13th September 1984

Mrs Marie W Tatt  
~~Registration Manager~~  
Miles Laboratories Limited  
Post Office Box 37  
Spoke Court  
Spoke Poges  
Slough SL2 4LY  
England

Re : KOATE - Dried Factor VIII Fraction PA 79/15/1-4

Dear Mrs Tatt

With reference to your application for the above product authorisation, in advance of dealing with the detailed Chemistry and Pharmacy matters outstanding following your replies of 23rd May last, I must inform you that :

- (1) As the Factor VIII preparations currently on the Irish market are all heat-treated for prevention of hepatitis transmission, the National Drugs Advisory Board would be unwilling to accept any Factor VIII products which were not similarly treated ;
- (2) Moreover, haematologists have indicated that they would be unhappy about using Factor VIII concentrates whose original plasma was collected within the areas associated with Acquired Immune Deficiency Syndrome. A written guarantee and evidence that Cutter does not collect source plasma for this product from any of the risk areas would be required to satisfy this point.

As these matters are fundamental to the continued consideration of this product, we would appreciate an early reply.

Yours Sincerely,

GRO-C

Mary Rafter (nee Smith)  
Pharmacist